August 31, 2026

The Honorable Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services Department of Health and Human Services
Attention: CMS-1850-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
Via online submission at www.regulations.gov.

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Oz:

We appreciate this opportunity to submit comments on behalf of five leading ophthalmology organizations regarding CMS-1850-P, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.* Collectively, our societies are responsible for performing nearly all of the ophthalmic surgical procedures performed in the US, most of which occur in the ophthalmic ASC setting.

The American Academy of Ophthalmology (AAO) is the largest association of eye physicians and surgeons in the United States. A nationwide community of over 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education, supporting research, and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care.

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 a particular interest in and commitment to advancing the art and science of ophthalmic surgery.

The American Society of Retina Specialists (ASRS) is the largest retinal organization in the world, representing over 3,500 members. Retina specialists are board-certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and enhance the ability of its members to provide the highest quality of patient 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 ambulatory surgical center (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. OOSS is a member of the ASC Quality Collaboration (ASCQC), a cooperative effort of organizations and companies interested in ensuring that ASC quality data is appropriately developed and reported.

The Society for Excellence in Eyecare (SEE) is a professional organization of ophthalmologists dedicated to educating its members about the most effective and advanced developments in ophthalmology, developing and implementing standards of practice for the effective and ethical provision of ophthalmologic services to patients, and serving as an advocate for patients in the promotion of high-quality, cost-effective eye care services.

On behalf of AAO, ASCRS, ASRS, OOSS, and SEE, we are taking this opportunity to comment on this important regulation governing CY 2027 Medicare ambulatory surgical center (ASC) payment rates and the Quality Reporting Program for ASCs. Importantly, we strongly support the agency's decision in 2019 to change the ASC update factor from the Consumer Price Index – Urban (CPI-U) to the Hospital Market Basket (HMB) and are pleased that this trial has been extended through 2027. We strongly believe that it should be adopted permanently. We are deeply disappointed with the agency's continued use of the scaler and its application of the 340B to the scaler. We will discuss other payment policy changes that should mitigate some of the distortions in relative payments to ASCs and hospital outpatient departments (HOPDs).

Since CMS decided more than a decade ago to overhaul the ASC payment system, our organizations have been engaged in discussions of ideas and review of data with the agency regarding the issues presented in this and recent rulemakings. We have appreciated the agency's willingness to work with the ASC industry, the ophthalmology community, and others and believe that there are many positive components in the proposed rule. With this spirit of cooperation and commitment to formulating a rational and sustainable ASC payment system, we join the ASC industry and other surgical specialty organizations in offering our specific comments below.

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SUMMARY OF RECOMMENDATIONS

Use of the Scaler to Establish ASC Payment Rates

- CMS should refrain from applying the weight scaler to the ASC payment system. If scaling is deemed necessary, CMS should combine the Outpatient Prospective Payment System (OPPS) and ASC utilization and case mixes to establish a single weight scaler.
- The proposed CY 2027 ASC weight scaler decrease, from 0.872 to 0.809, driven by the proposed 340B drug payment policy, would disproportionately cut payment for ophthalmic surgery. Our organizations cautiously support CMS's proposed alternative of including device portions of device-intensive procedures in the ASC weight scaler calculation, which lessens the impact on non-device-intensive procedures. Though, ultimately in future rules, we believe the best solution is to remove the ASC weight scaler altogether.

Annual ASC Payment Updates

- We applaud the agency's decision to maintain the HMB as the ASC update factor through 2027. If CMS elects to collect data to establish a new ASC-specific market basket, the agency should expand its analysis to create an index that will be applied to both the HOPD and ASC to ensure that payments using the same relative weights remain aligned over time.

Access to Retina Surgical Care

- Retinal detachment repair is reimbursed well-below the cost to an ASC of providing the surgery, forcing ASCs to limit or discontinue offering this surgery. CMS should protect access to this care in the ASC setting by increasing reimbursement for 67108 and 67113.
- CMS should implement an Ophthalmic Emergency Activation (OEA) coding and payment policy that would recognize the additional costs of providing emergency ophthalmic care.

Dextenza

- CMS should (1) assign CPT code 68841 to Ambulatory Payment Classification (APC) 5503 with a different status indicator that allows for separate payment in the ASC setting (e.g., "J1")
- Should CMS establish a different payment methodology for 340B acquired drugs, it should finalize the proposal to exempt non-opioid pain management drugs from such payment methodology and continue to pay for such drugs at average sales price (ASP) plus 6 percent.
- In the final rule, CMS should detail its findings from implementation of section 4135 of the Consolidated Appropriations Act of 2023 (CAA) and how it intends to ensure continued access to non-opioid treatments for pain relief when this provision sunsets on January 1, 2028**.**

Access to Non-Opioid Pain Management

- CMS should use separate regulatory authority to establish separate payment for non-opioid products, which is not limited by the 2025-2027 timeline under CAA 2023 and ensure continuity of payment policy by extending separate payment for non-opioid products beyond 2027
- CMS should develop a policy that covers drugs that are administered at the time of ophthalmic surgery, that are direct substitutes for postoperative medications, or that have an FDA-approved indication to treat/prevent post-operative issues, such as pain, inflammation, or infection, separately under Medicare Part B.

Payment for Drug-Eluting System and Procedures/MIGS

- CMS should maintain pass-through status for HCPCS code J7355 through June 30, 2027, and upon pass-through status expiration effective July 1, 2027, assign the drug a K status indicator.
- CMS should finalize the proposal to assign CPT codes 0660T and 0661T to APC 5492 but revise the status indicator for both services to "S" to ensure the sufficiency of

payment levels for the combination of these procedures and the furnished drug throughout CY 2027.

- ❖ CMS should finalize the proposal to continue to assign CPT codes 66989, 66991, and 0671T to APC 5493. CMS should finalize the proposal to continue to designate CPT codes 66989, 66991, and 0671T as device-intensive procedures and determine the ASC payment rates accordingly.
- ❖ For all drugs and devices with pass-through status expiring during the upcoming calendar year (i.e., end of March, end of June, and end of September), in the pertinent OPPS proposed rule, CMS should propose the status that it would provide for each product so that the public has the opportunity to comment during the rulemaking process.
- ❖ CMS should evaluate the impact of implementing a drug-intensive procedure policy like the device-intensive procedure policy and present the findings in future rulemaking.

Extension of Expiring Pass-Through Devices

- ❖ CMS should revise its approach to expiring pass-through products to ensure the public has a meaningful opportunity to comment on what transpires with a product upon expiration of pass-through status.

Assignment of CPT 0730T to APC 5493

- ❖ CMS should finalize the proposed rule to assign CPT code 0730T to 5493 and designate CPT code 0730T as device-intensive to ensure that Medicare beneficiaries have access to this technology in the most appropriate setting.

Reassignment of CPT 0563 to APC 5503

- ❖ Our organizations believe that CPT 0563 should be reassigned to *APC 5503, Level 3 Extraocular, Repair and Plastic Eye Procedures,* which is a more clinically appropriate and resource-homogeneous APC

Skin Substitutes

- ❖ Because non-sheet products perform the same or similar functions to sheet versions and are derived from the same source material, we support inclusion and coverage of non-sheet formulations (including powders, gels, ointments, foams, liquids, and injected products).

New Technology IOL

- ❖ To meet CMS' original objectives to enable Medicare beneficiaries' quick access to new technologies, we strongly encourage CMS to consider increasing the NTIOL per lens payment from $50 to $100 in CY 2027.

Unlisted Codes

- ❖ CMS should revise the Federal Code of Regulations to eliminate the restriction on billing with unlisted codes.

Hospital Prior Authorization Expansion

- ❖ CMS must resolve the program's existing operational and evidentiary problems in the HOPD setting before expansion of prior authorization is considered.

Interim Software as a Medical Service (SaMS) Reimbursement Policy

- ❖ We appreciate the agency's consideration of an interim reimbursement framework for SaMS. We ask that CMS commit to a timeline for developing a permanent methodology through notice-and-comment rulemaking.

ASC Quality Reporting

- ❖ While we support the agency's recent decision to keep reporting of ASC-11 voluntary through at least the 2031 payment determination year, our organizations strongly believe that ASC-11 should be withdrawn from the program altogether.
- ❖ CMS should include the TASS measure in the ASCQR program.
- ❖ If an ASC is operational with the OAS Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, it should not be penalized if fewer than 200 patients complete the survey.

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THE OPHTHALMIC ASC AND THE POTENTIAL TO ACHIEVE SIGNIFICANT SAVINGS TO THE MEDICARE PROGRAM AND BENEFICIARIES

In formulating ASC policy and establishing payment rates, the agency must recognize that most ASCs are small businesses that need to run efficiently to remain in operation. There are over 6,000 Medicare-certified ASCs – about 1,400 of which specialize in ophthalmology – and over half have only one or two operating rooms. Our facilities purchase the same equipment, devices, implants, and supplies as HOPDs and must compete with hospitals for the same nurses and other personnel, while complying with the same federal and state patient health and safety requirements and the ever-growing demands of the Medicare ASC Quality Reporting program. Our centers operate efficiently; however, receiving reimbursement that is about half that of competing hospital facilities compromises the ability of ASCs to continue to provide the care and technology that Medicare beneficiaries deserve.

The potential for Medicare to derive savings from the migration of services from the hospital to the ASC is substantial. We draw your attention to a study by the KNG Group, *Medicare Cost Savings Tied to Ambulatory Surgery Centers,* which concluded that annual Medicare cost savings attributable to ASCs increased from $3.1 billion in 2011 to $4.1 billion in 2018. (Ophthalmology accounted for more than one-third of the savings.) Importantly, if volume migration continued at the same rate as in 2011-2018, surgery centers were projected to save Medicare $74.2 billion from 2019-2028. That said, payment policy reform (such as elimination of the ASC weight scaler and corrections to the calculation of base facility rates) is necessary to further the migration of appropriate procedures from the hospital to the lower cost surgery center

setting and to ameliorate the widening disparity between the rates paid to HOPDs and ASCs.

In May of this year, KNG Consulting, LLC issued a report, *Medicare Savings From Use of Ambulatory Surgery Centers, 2019-2024,* a follow-up to a similar 2019 report. The study demonstrates that ASCs, particularly those oriented to ophthalmic surgery, have been a driving force in saving billions of Medicare dollars and that this trend will continue over the next decade. A few highlights:

- From 2019-2024, the Medicare savings generated by procedures performed in ASCs instead of hospitals totaled $27.9 billion. *Cataract and related services accounted for $10.4 billion, or 37 percent of the savings to Medicare.*
- For the period 2025-2034, ASCs are projected to save $84 billion in FFS Medicare. *Cataract and related services are expected to account for 27.9 percent of these savings.*
- *For the period 2019-2034, ophthalmic services in an ASC will account for $25 billion in savings to Medicare.*

Under the proposed rule, facility payment for cataract surgery with IOL (66984) in 2027 would be $1,212 (reduced from $1,256 in 2026) in the ASC setting, while reimbursement for the same procedure in the HOPD would be $2,699. The beneficiary's financial obligation in the form of copayments would be $244 in the ASC and at least $540 in the HOPD; patient cost-sharing is always lower in the ASC, a benefit for the beneficiary. Therefore, for each cataract operation performed in an ASC instead of an HOPD, the program would save $1,191 and the beneficiary $296 for an aggregate savings of $1,487 or more. With more than two million cataract surgery cases performed each year for Medicare fee for service beneficiaries, the impact of savings to the program and the beneficiary by performance of cataract surgery in the ASC is, as documented in the KNG study referenced before, well into the billions of dollars annually. While ASCs perform about 75 percent of cataract surgeries, there is still significant opportunity for volume migration as virtually every cataract operation can be safely and effectively performed in ASCs.

As discussed in detail below, the agency's continued utilization of rescaling to achieve budget neutrality in the 2027 proposed rule, as well as recent reclassifications of procedures into new APCs and packaging policies, has exacerbated distortions in payment rates to ASCs and hospitals. In a very real sense, these policies compromise the integrity of the ASC payment system, reduce realizable program savings, and inhibit transparency regarding price and quality among Medicare providers, thereby jeopardizing beneficiary access to affordable, high-quality surgical care. We believe that adoption of our recommendations will enable Medicare to achieve savings for the program and the beneficiary while maintaining the quality of care that is delivered in the ASC.

THE WEIGHT SCALER AND ANNUAL ASC PAYMENT UPDATE

CMS Should Discontinue Use of the Scaler in Calculating ASC Rates

AAO, ASCRS, ASRS, OOSS, and SEE strongly believe that CMS should eliminate rescaling of the ASC relative weights, as this practice has exacerbated the gap between ASC and HOPD payments and inequitably reduced payments to ASCs without evidence of growing differences in capital and operating costs in the two settings. In 2003, aggregate ASC payments as a percent of HOPD rates were 85 percent. Since the new system was established in 2008, the ratio of ASC rates to HOPD rates has dropped to 65 percent; under the proposed 2027 rates,

Medicare will reimburse ASCs, on average, 50 percent less than HOPDs performing the same procedures. We note that whereas ASCs accounted for 6.63 percent of total Medicare expenditures in 2016, the ASC percentage of that spend has declined, representing only 5.9 percent in 2022.

This situation is the result of the application of the scaler to ASC weights. It is entirely unrelated to the cost of providing services to Medicare patients within the respective outpatient surgical environments. At a time when ASCs offer the very real potential of augmenting access to high-quality services at substantially lower cost, policymakers and the public should be concerned about the growing risk of surgery migrating back to the higher-cost HOPD. Since the advent of the new payment system, hospital market share is growing for many high-volume procedures.

As we have noted in our comments to past ASC payment rulemakings, our organizations support the utilization of the same APCs and relative weights in creating a rational and coherent payment system encompassing the services offered by both HOPDs and ASCs:

> ". . . the rescaling of ASC relative weights . . . will result in further divergences in weights and payments, exacerbating exactly the types of distortions that the new system was presumably intended to correct. The only legitimate basis for change in relative payments to HOPDs and ASCs should be changes in the relative costs of providing specific outpatient services. There is little basis for believing that these variations will occur, and to the extent that they do, they should be accounted for directly through adjustments to the conversion factor."

Of note, APC relative weights are already adjusted once for budget neutrality. Contrary to CMS' assertion in 2007 that rescaling would protect ASCs from decreases in payments for procedures due to changes in OPPS relative weights, experience since that time reflects otherwise. The rescaling adjustment has had the opposite effect, decreasing the relative weights on ASC surgical procedures each year. Since 2010, our relative weights have decreased by an average of 7 percent each year. There is no evidence to suggest that there are growing differences in capital and operating costs in the two settings to support such an accelerating differential. **This historical trend, as well as the agency's proposed 340B policy change discussed below, suggests that the application of the weight scaler in the ASC environment will continue to erode the relationship between ASC and HOPD payments.** The agency is increasing Medicare program costs by making it financially impracticable to furnish services that are clinically appropriate for the ASC, and, hence, pressing physicians to perform these procedures in the more expensive HOPD setting. **We strongly recommend that the agency discontinue use of the scaler**, which penalizes care in the most efficient, yet equally safe, setting.

We note that CMS is not required to maintain rescaling. Congress imposed a budget neutrality requirement on the new ASC payment system *only* during the inaugural implementation year of 2008; CMS is under no legal obligation to continue to apply rescaling and should not do so when it creates significant disparities in relative payments to ASCs and hospitals that are not related to the costs incurred in providing such services. Therefore, we implore the agency to encourage savings and greater access to ASCs for Medicare beneficiaries by eliminating the ASC weight scaler.

Our organizations realize that the elimination of the ASC weight scaler would increase Medicare program costs, at least initially, until cost savings are achieved by volume shifting to the ASC setting. As an alternative, **we propose that CMS refrain from applying the secondary weight scaler to the ASC payment system and, instead, combine the OPPS and ASC utilization and case mixes to establish a single weight.** By incorporating the ASC volume into OPPS weight calculations, CMS would improve the alignment of the payment systems and more accurately scale for outpatient volume across both sites of service.

Now, eighteen years after the implementation of the ASC payment system, it is past time for CMS to analyze the drivers of continuing increases in the OPPS and whether such factors should or should not be offset in the ASC setting.

CY 2027 OPPS Payment Methodology for 340B Purchased Drugs Based on Survey Results

CMS proposes to replace the long-standing Medicare payment methodology for most 340B-acquired drugs with a new acquisition cost-based approach, paying such drugs at average sales price (ASP) minus 33.4 percent while continuing to pay non-340B drugs at ASP plus 6 percent, which CMS determined from the recent 340B Drug Cost Acquisition Survey. Because this change must be implemented in a budget-neutral manner, CMS proposes an 8.44 percent increase to the OPPS conversion factor for non-drug items and services for CY 2027. The agency also proposes increasing the annual OPPS conversion factor reduction associated with the 340B remedy from 0.5 percent to 3 percent, significantly accelerating recovery of prior budget neutrality payments.

As discussed below, the budget-neutral redistribution associated with this policy has significant downstream consequences for ASC reimbursement that our organizations urge CMS to address before finalizing this rule.

ASC Payment Rates, the Hospital Market Basket Update, and the ASC Weight Scaler

Our organizations continue to strongly support CMS's decision to apply a productivity-adjusted HMB update, rather than the Consumer Price Index-Urban, to ASC payments for CY 2027. The HMB reflects the actual cost growth experienced by ASCs, which purchase the same equipment, devices, implants, and supplies as HOPDs and compete for the same clinical staff. To provide predictability and stability for the ASC payment system, we urge CMS to make this policy permanent rather than continuing to extend it on a year-by-year basis.

However, our organizations are deeply concerned that the positive, overall 2.4 percent proposed update to HOPD and ASC payment rates for CY 2027 obscures a sweeping, unintended cut to ASC reimbursement for most ophthalmic surgical procedures. CMS's proposed ASC weight scaler is a substantial decrease from 0.872 in CY 2026 to 0.809 in CY 2027. As CMS explains in the proposed rule, this decrease is attributable to a large increase in the device portions of device-intensive procedures, which are held constant between the OPPS and ASC payment systems and have been excluded from the expenditures subject to ASC weight scaler calculations. Because the proposed 340B drug payment policy would increase OPPS payment rates for surgical procedures on a budget-neutral basis, it correspondingly increases the device portions of device-intensive procedures, which in turn forces a larger downward rescaling of the non-device portions of all other ASC-payable services to maintain budget neutrality.

The result is a policy that indirectly, but substantially, reduces ASC reimbursement for specialties like ophthalmology that have comparatively few device-intensive procedures. CMS itself estimates that overall CY 2027 ASC expenditures for ophthalmic surgery would decrease by 1 percent under this proposal, notwithstanding the overall positive update. ASC facility reimbursement for several of the most common ophthalmic procedures would be cut far more significantly, including:

- Cataract surgery (CPT 66984) — -3.5%
- Canaloplasty (CPT 66174) — -3.1%
- Retinal detachment repair (CPT 67108 and CPT 67113) — -3.1%

These reductions are especially troubling because they run counter to the anticipated HOPD reimbursement. For example, HOPD reimbursement for CPT 66984 would increase by approximately 13 percent under the proposed rule; only the ASC setting, where most cataract surgery and other ophthalmic surgery is performed, bears the cost of the offsetting reduction. Ophthalmic ASCs are single- or dual-specialty small businesses with little ability to absorb across-the-board facility fee reductions of this magnitude, and reduced reimbursement for high-volume, medically necessary procedures like cataract surgery, canaloplasty, and retinal detachment repair directly threatens beneficiary access to sight-saving care, particularly for time-sensitive conditions such as retinal detachment. We are concerned that this policy with any future increases will incentivize market consolidation and the sale of privately-owned ASCs to larger private equity entities and hospitals, raising the cost of care.

Notably, CMS has solicited stakeholder feedback on an alternative approach: including the device portions of device-intensive procedures within the expenditures subject to ASC weight scaler calculations. CMS estimates that this alternative would raise the proposed ASC weight scaler from 0.809 to 0.865 for CY 2027, while reducing the device portion of payment for device-intensive procedures by approximately 14 percent.

Our organizations cautiously support this alternative approach. Including device portions within the ASC weight scaler calculation would raise the scaler and mitigate cuts to non-device-intensive procedures, maintaining access to many vision-restoring ophthalmic surgeries. We are cautious of the alternative approach because it will be incumbent upon device manufacturers to make their product available to ASCs at a cost covered by scaled rate. We ask that CMS closely monitor the impacts of this significant policy change, particularly on patient access and site-of-service shifts.

Annual ASC Payment Update and Request for Cost Data

As we have emphasized in our comments in recent years, our organizations strongly support the agency's decisions to change the ASC update factor from the CPI-U to the HMB at least through 2027. The CPI-U does not reflect ASC cost growth and the HMB is a better proxy for ASC cost increases. ASCs and HOPDs treat the same patients for the same conditions, consume commensurate resources, and incur similar costs. Application of different inflation factors has unjustly expanded the gap in payments to HOPDs and ASCs. We believe that applying the same update factor to both types of facilities will promote appropriate migration of suitable services from the HOPD to the ASC, generating significant cost savings to the Medicare program and the beneficiary.

Aligning conversion factors – in addition to eliminating the scaler, as discussed below – will equitably level the playing field between hospital and freestanding surgical facilities. **We applaud the agency's decision to maintain the HMB as the ASC update factor through 2027, and we look forward to collaborating with CMS as it makes its determination regarding an appropriate update factor for ASCs.**

CMS has expressed a desire to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner. For the reasons stated above, we believe that the HMB is an appropriate update factor for ASCs. **If CMS elects to collect data to establish a new ASC-specific market basket, the agency should expand its analysis to create an index that will be applied to both the HOPD and ASC to ensure that payments using the same relative weights remain aligned over time.** In developing a data collection modality, CMS should keep in mind that ASCs incur significant administrative burdens in complying with current regulations; requiring formal cost reports would diminish the agency's commitment to promulgate rules and policies that allow facilities to maintain efficiency in the delivery of services to our patients. We look forward to collaborating with CMS on this endeavor.

ACCESS TO RETINA SURGICAL CARE in the ASC and HOPD

We continue to be concerned that CMS has not addressed the national trend of reduced ASC access for retinal surgery, despite acknowledging the issue in the final 2026 OPPS/ASC payment rule. While we appreciate the proposed CY 2027 payment increases for retina procedures furnished in HOPDs, these increases result from unrelated budget neutrality adjustments and do not address the underlying payment inadequacy in the ASC setting. In fact, those same budget neutrality adjustments, combined with the secondary rate scaler discussed elsewhere in this letter, would further reduce ASC payment rates and exacerbate existing access challenges. We strongly urge CMS to take immediate action, such as implementing an ophthalmic emergency activation (OEA) coding and payment policy, to ensure ophthalmic ASCs are adequately reimbursed for the resources required to furnish sight-saving surgery when emergency cases occur.

Lack of Access to ASCs and Hospitals for Retina Surgery

A targeted ASRS operating room access survey conducted in 2026 found that 90% of respondents were experiencing OR access issues—a significant increase from the 2025 ASRS Preferences and Trends (PAT) survey that found more than 71% of 889 retina specialists responding reported OR access difficulties. Access remains particularly limited for emergent cases such as retinal detachment repair.[1] Many retina specialists report either having their ASC surgical block time reduced or eliminated completely. For beneficiaries suffering these potentially blinding conditions, the longer they must wait for surgery, the more likely they are to have a poor outcome.

Inadequate facility reimbursement remains the primary cause of reduced access for these surgeries. For retinal detachment repair (67108), the proposed CY 2027 OPPS payment rate of $4827.36 represents a $300.94 loss per case, when compared against the geometric mean for the

[1] Hahn P, ed. ASRS 2025 Preferences and Trends Membership Survey. Chicago, IL. American Society of Retina Specialists; 2025

procedure of $5128.30. These financial losses are just as significant for ASCs. Facilities cannot afford to allocate enough time to meet the patient demand when they are losing several hundred dollars on each case. Importantly, the geometric mean reflects an average across cases; the cost of individual cases can be substantially higher depending on the complexity and duration of the surgery and the surgical techniques required, such as scleral buckling.

Peer-reviewed studies confirm these trends. A study found that scleral buckling in particular adds time to the case and cost.[2] At a mean cost per case of $7674.64, facilities incur a $2713.64 loss compared with the Medicare payment of $4961. The same study also gathered data from numerous prior studies demonstrating substantial variation in procedure times for both scleral buckling and pars plana vitrectomy, another commonly used surgical technique.

Another study found that retinal procedures required an average of 90.5 minutes with a cost of approximately $6250 per case, well above the average Medicare reimbursement of $5443. At current reimbursement levels, the time to perform retinal procedures would have to decline to approximately 65 minutes for ASCs to break even.[3] Offering retinal surgeries has become an opportunity cost for ASCs when they could make more predictable and adequate revenue to meet their operating costs by focusing on other services.

Ophthalmic Emergency Activation (OEA) Coding and Payment

Beyond the additional time necessary to complete retinal cases, ophthalmic ASCs incur costs associated with maintaining emergency surgical readiness to accommodate unscheduled, time-sensitive cases. Patients suffering sight-threatening conditions, such as retinal detachments, open globe injuries, intraocular foreign bodies, and endophthalmitis need immediate surgical intervention, and surgery centers must be equipped with trained personnel, specialized equipment, and other standby resources to provide it. Because Medicare's reimbursement does not account for these costs, ASCs face the difficult decision of whether to continue offering emergency retinal services, or retinal care altogether. When community-based ASCs are unable to provide emergency ophthalmic care, beneficiaries are often forced to travel significant distances to already overburdened academic medical centers to receive necessary time-sensitive care, while also facing higher out-of-pocket costs associated with receiving their care in the HOPD setting.

As a solution to this growing public health crisis, we urge CMS to implement an OEA coding and payment policy that would recognize the additional costs of providing emergency ophthalmic care. Modeled on Medicare's existing trauma activation framework, the OEA policy would provide an additional payment to recognize the standby capacity, resource intensity, and disruption associated with furnishing acute, unscheduled ophthalmic surgical care. A facility-level add-on of 50% to the applicable OPPS or ASC rate, and 25% add-on to the Medicare physician fee schedule payment amount would help address the difference between the geometric mean cost of these procedures and current and proposed payment levels. To mitigate program integrity and utilization concerns, the OEA policy would only be triggered when defined clinical and operational criteria for a qualifying ophthalmic emergency are met, with documentation and attestation requirements to ensure appropriate use. Under such a policy,

[2] Blumenthal J, et. al. Operative Times in Scleral Buckle Surgery: Influencing Factors and Cost Analysis. *J Vitreoretin Dis*. 2024;9(1):18-25.,

[3] Busquets M, et. al. A Comparative Time-Based Profit Analysis of Retinal and Cataract Surgery in Ambulatory Surgery Centers. *J Vitreoretin Dis.*2026;10(6):1-7.

Medicare and beneficiary out-of-pocket costs in the ASC would remain lower than if the care were furnished in a hospital setting, while improving the likelihood that beneficiaries can access timely care in a community-based setting and achieve a good clinical outcome.

The reductions to ASC payment proposed in this rule are likely to exacerbate these existing access challenges. We urge CMS to take immediate action, including through implementation of the proposed OEA policy, to ensure adequate payment for these services and preserve beneficiary access to sight-saving care in the lower-cost ASC setting. Additionally, we ask CMS to evaluate additional intraocular APC level(s) that better reflect the cost of complex retinal surgeries as a potential solution to the growing access crisis.

DEXTENZA (J1096) AND INSERTION PROCEDURE (CPT 68841)

Dextenza is the only FDA-approved ophthalmic intracanalicular insert that delivers dexamethasone to the ocular surface for up to 30 days. It is indicated for (1) ocular inflammation and pain following ophthalmic surgery in adults and children, and (2) ocular itching associated with allergic conjunctivitis in patients ≥2 years. To insert Dextenza, the punctum is anesthetized and dilated and then it is inserted into the canaliculus. The procedure, reported with CPT code 68841, is performed about 80% of the time in the ASC setting. Dextenza replaces the use of self-administered eye drops, which carry adherence and administration challenges — particularly among older patients with dexterity, vision, or mobility limitations. Further, Dextenza is preservative-free, whereas eye drops commonly contain benzalkonium chloride (BAK), a preservative toxic to the ocular surface that induces oxidative stress, inflammation, and ocular surface disease, raising long-term costs and less optimal treatment outcomes.

CMS proposes assigning CPT 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures), but with a "Q1" status indicator, which problematically yields no separate ASC payment. For cost-sensitive ASCs, as CMS has noted, the lack of payment for the procedure is a disincentive to use Dextenza and requires beneficiaries to use alternatives such as eye drops. CMS's proposal also treats this procedure differently than the about 75 other procedures assigned to APC 5503, which have a J1 status indicator (allowing for separate payment to ASCs). The proposal also treats CPT code 68841 differently than other comparable drug delivery procedures – CPT codes 66030, and 0699T – that also have J1 status indicators and payment in the ASC setting.

Previously, CMS justified not making CPT code 68841 separately payable due to a low level of single frequency claims. That, too, treats this code differently from other similar situations. For example, Exparel (J0666), is another non-opioid post-surgical treatment for which the insertion procedure (CPT code 64415) has as low a single frequency claim rate as CPT code 68841 and has a status indicator that fosters separate payment in the ASC setting (a "T" status indicator). Further, many other procedures with ≤2% single frequency claims have separately payable status indicators. CMS should assign CPT code 68841 a status indicator (e.g., J1) that allows payment in the ASC setting to facilitate better treatment for ocular pain and itching and end the arbitrary treatment of this procedure compared to other similar procedures.

For the reasons detailed above, CMS should (1) assign CPT code 68841 to APC 5503 with a different status indicator that allows for separate payment from the medication in the ASC setting (e.g., "J1".)

PAYMENT FOR NON-OPIOID PAIN MANAGEMENT

Exempting Non-Opioid Pain Management Drugs from the Proposed Payment Methodology for 340B Purchased Drugs

Based on the findings of a hospital acquisition cost survey, CMS proposes to pay for 340B drugs acquired under the 340B Program at average sales price (ASP) minus 33.4 percent. As part of this proposal, CMS would exempt non-opioid pain management drugs from this payment methodology such that those drugs would continue to be paid at ASP plus 6 percent. We agree with CMS that a revised payment methodology for non-opioid pain management drugs would be inconsistent with the Medicare statute at section 1833(t)(16)(G) of the Social Security Act such that should CMS finalize a different payment methodology for 340B purchased drugs, it must finalize the exemption for non-opioid pain management drugs.

Ensuring Continued Access to Non-Opioid Treatments for Pain Relief

Pursuant to section 4135 of the *Consolidated Appropriations Act, 2023* ("CAA 2023"), separate Medicare payment has been made for non-opioid treatments for pain relief in both the hospital outpatient and ASC setting starting January 1, 2025. These provisions directed the Secretary to provide separate payment for qualifying non-opioid products in calendar years (CYs) 2025, 2026, and 2027. The timeline under these provisions creates uncertainty as to Medicare payment levels for qualifying non-opioid products in 2028 and future years. The separate payment provisions from CAA 2023 have been helpful in facilitating options to meet the post-operative challenges that our patients face and thus it is imperative that the expiration of the CAA 2023 provisions does not impede our ability to continue to use those options.

We urge CMS to make use of its separate regulatory authority to establish separate payment for non-opioid products, which is not limited by the 2025-2027 timeline under CAA 2023, and ensure continuity of payment policy by extending separate payment for non-opioid products beyond CY 2027. We also ask that CMS include a discussion in the final rule that provides an analysis of the impact of separate payment for non-opioid treatments for pain relief and to share its views on potential approaches to ensure that access to these items and services can be maintained as of January 2028. That will afford the public a more meaningful opportunity to present ideas to CMS in early 2027 on how to address future payment policies.

Expanding the Definition of Non-Opioid Drugs

To date, CMS has paid separately in the ASC for only a very limited number of non-opioid pain management drugs. Specifically, AAO, ASCRS, ASRS, OOSS, and SEE are concerned with the bundling of FDA-approved drugs that are administered at the time of ophthalmic surgery—either before, during or at the end of the procedure— and which can be substituted for postoperative administration of drugs which have an indication for the treatment of post-operative pain and/or inflammation and/or other sequela of the surgery.

For example, topical dexamethasone eye drops are a drug commonly used in ophthalmology because of longstanding evidence that it reduces post-operative inflammation, and therefore pain following cataract surgery. Some drugs that have the active ingredient dexamethasone, such as Dextenza, are already indicated by FDA for both ocular inflammation

and pain. Others, such as Dexycu, are indicated for post-operative inflammation alone. *The agency should not treat FDA-label differences as determinative as to whether a drug like Dexycu can be designated as a non-opioid pain management drug. Inflammation following ocular surgery is a major risk factor for pain*. Ocular inflammation induces activation of neurons within the sensory trigeminal complex; altered activity in intracellular signaling caused by ocular inflammation also plays a role in the sensitization of ocular-related brainstem circuits, leading to the development of ocular pain. By reducing inflammation, ophthalmic dexamethasone reduces a key risk factor associated with post-operative pain.

Ophthalmologists and our patients are fortunate to have multiple options to meet the post-operative challenges our patients face, including excellent self-administered medications as well as innovative and effective surgeon-administered drugs. Our members and facilities believe that patients should be afforded the option of using self-administered eye drop medications post-procedure (Part D products) or to have FDA-approved drug products administered by the surgeon at the time of the ophthalmic surgery (Part B products). **Therefore, we urge CMS to develop a policy that covers drugs that are administered at the time of ophthalmic surgery, that are direct substitutes for postoperative medications, or that have an FDA- approved indication to treat/prevent post-operative issues, such as pain, inflammation, or infection, separately under Medicare Part B.**

PAYMENT FOR ANTERIOR SEGMENT DRUG-ELUTING SYSTEM AND PROCEDURE/MIGS

IDose TR® (travoprost intracameral implant) (HCPCS Code J7355) is a drug administered intracamerally through a corneal incision and anchored into the sclera and is used to replace daily ocular hypertensive eye drop treatments. iDose TR currently has pass-through status; however, that status will expire effective July 1, 2027. Just as CMS has done with other drugs coming off pass-through that are inserted into the eye (e.g., J2779, J7351), CMS should provide separate payment at the applicable ASP methodology-based payment (i.e., assign a K status indicator to J7355) once J7355's pass-through status ends. **As a result, and in line with CMS's past precedent for similar products, CMS should make it clear that iDose TR will have a K status indicator at the expiration of pass-through status, ensuring that it remains separately payable throughout the entirety of 2027, not just the first six months.**

CPT codes 0660T and 0661T are used to report administration of iDose TR. Both codes have a J1 status indicator. Since the codes became payable under OPPS in 2024, they have been appropriately assigned to APC 5492 and are proposed to continue with that assignment in 2027, which we support. As discussed above, separate payment for iDose TR will be effectuated with a K status indicator effective July 1, 2027, replacing the current G status indicator for J7355 and subjecting iDose TR to CMS's comprehensive APC (C-APC) packaging policy. This would mean that in the second half of 2027, there would be payment for the implant procedure under APC 5492, but no payment made for iDose TR under the C-APC packaging policy. The proposed payment rate for APC 5492 is lower than the cost of iDose TR alone, and the lack of payment will likely lead to reduced access and reduction of data available to CMS. **To avoid this result, we recommend that CMS continue its assignment of 0660T and 0661T to APC 5492 but alter the status indicator for the codes from J1 to S to allow for continued separate payment for both the drug and procedure code throughout 2027.**

Micro-invasive glaucoma surgery (MIGS) may be performed with a cataract procedure or without a cataract procedure. CPT codes 66989 and 66991 are used to report a MIGS procedure with a complex and routine cataract procedure, respectively, while CPT 0671T is used to report a MIGS procedure that is performed without a cataract procedure. CMS proposes for 2027 to continue to assign these procedures to APC 5493, in the Intraocular Procedures APC family. Hospital outpatient claims data show geometric mean cost figures for all three procedures that are consistent with the geometric mean costs for procedures assigned to APC 5493. **As a result, we recommend that CMS finalize the proposal to maintain the assignment of CPT codes 66989, 66991, and 0671T to APC 5493.**

Since most of these procedures are performed in the ASC setting, it is critical to ensure the payments cover the cost of the device and performing the surgery. Designating CPT codes 66989, 66991 and 0671T as device-intensive is necessary to achieve this objective. **Therefore, we recommend that CMS finalize continuing the device-intensive designation for CPT codes 66989, 66991, and 0671T for CY 2027, and determine the ASC payment rate for these codes accordingly.**

EXTENSION OF EXPIRING PASS-THROUGH DEVICES

Each year, several drugs and devices have their pass-through status expire in the middle of the calendar year (e.g., as of April 1, July 1, or October 1). For example, in Table 44 of the Proposed Rule, CMS notes that 28 drugs will have pass-through status expire on March 31, 2027, June 30, 2027, or September 30, 2027. CMS does not indicate how it will treat these products when pass-through status expires, leaving the health care community to ascertain the status for each when the product appears in a quarterly OPPS update transmittal without the opportunity for public input on such treatment.

CMS should revise its approach to expiring pass-through products to ensure the public has a meaningful opportunity to comment on what happens to a product upon expiration of pass-through status. Each year's OPPS rulemaking process provides a vehicle for doing so. For example, for a product with pass-through status expiring on March 31, 2028, CMS should include in the CY 2028 OPPS proposed rule, how it proposes to treat the product and an explanation of why it is doing so. The public would then have the opportunity to comment on that proposal, and CMS could make its final decision after consideration of comments received, all as part of the CY 2028 rulemaking process. This would greatly increase transparency as to the treatment of pass-through products and ensure that the appropriate decision is made on the front end.

DRUG-INTENSIVE POLICY FOR ASC PAYMENT

CMS has established a policy in the ASC rate setting process that allows the ASC rates to reflect their costs of devices that are relatively costly compared to the payment rate of the procedure in which the device is used. As the agency is aware, for device-intensive procedures, the ASC payment rate is currently computed differently than procedures that are not device-intensive – only the non-device portion of the OPPS rate for the procedure is subject to the ASC conversion factor. We agree with CMS that this mechanism allows for a more accurate representation of the costs attributable to such devices.

The logic behind this device-intensive policy is equally applicable to situations where a drug that is packaged into a procedure is costly compared to the procedure. Just as with medical devices, ASCs typically do not pay less than hospitals for costly drugs; as such, there should be a similar drug-intensive policy for calculating ASC rates for procedures in which a costly drug is packaged into the payment for the procedure, so the ASC rates more accurately represent the cost of such drugs. We encourage **CMS to evaluate the impact of a drug-intensive policy for ASC rate setting, along the lines of the current device-intensive policy** and share the analysis in future rulemaking.

ASSIGNMENT OF CPT 0730T to APC 5493

We support CMS's decision to assign CPT code 0730T, which refers to trabeculotomy by laser with optical coherence tomography (OCT) guidance, to APC 5493. We urge CMS to maintain this assignment in the final rule for CY 2027. Additionally, we support designating CPT code 0730T as device intensive to ensure that Medicare beneficiaries have access to this technology in the most appropriate setting.

CPT code 0730T is inherently dependent on specialized technology to perform the procedure as described. The procedure involves a dedicated femtosecond laser platform equipped with integrated OCT imaging, specialized software, and a unique patient interface. These technologies work together to provide image-guided visualization and laser treatment of the trabecular meshwork without the need for an eye incision. Unlike conventional incisional goniotomy, this technology allows for precise incision-free laser treatment through an external, image-guided approach.

AAO, ASCRS, OOSS, ASRS, SEE, and American Glaucoma Society have long advocated for policies that facilitate safe and efficient ophthalmic procedures in ambulatory surgical centers (ASCs). The appropriate implementation of the device-intensive policy ensures that Medicare facility payments adequately acknowledge the device costs required for these procedures and prevent inadvertently creating barriers to their availability in ASC settings. Without device-intensive status, the payment disparity between hospital outpatient departments and ASCs may unintentionally create a financial disincentive to performing CPT 0730T in ASCs, despite the procedure being well-suited to the ASC environment. This outcome would contradict Medicare policies that encourage beneficiaries to receive appropriate outpatient surgical care in efficient, cost-effective settings when clinically appropriate.

As ophthalmic care transitions towards less invasive, image-guided, and device-dependent procedures, Medicare payment policy should appropriately recognize the costs associated with providing these services. Designating CPT 0730T as device-intensive would help maintain beneficiary access, support the availability of the procedure across suitable outpatient settings, and prevent a payment-driven incentive favoring the higher-cost hospital outpatient setting.

REASSIGNMENT OF CPT 0563T TO APC 5503

CPT 0563T describes evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral. TearCare is

a technology-enabled interventional therapy for meibomian gland disease (MGD) that continuously heats all four eyelids to a therapeutic temperature to melt or liquefy hardened oil obstructions in the meibomian glands, followed by physician-performed manual evacuation of the glands.

Under the CY 2027 OPPS proposed rule, CPT 0563T remains assigned to APC 5733, Level 3 Minor Procedures, with a proposed payment of approximately $67. We do not believe this assignment appropriately reflects either the clinical nature of the procedure or the resources required to furnish it. TearCare requires specialized capital equipment, single-use bilateral treatment components, treatment of all four eyelids, clinical staff and treatment-room resources, followed by physician-performed manual evacuation of the meibomian glands. The single-use treatment components alone have a cost that substantially exceeds the proposed APC 5733 payment.

TearCare is performed predominantly in the physician-office setting, where utilization does not generate an OPPS facility claim. Therefore, the limited HOPD claims reflect where TearCare is currently performed rather than the resources required to furnish the procedure. We do not believe these limited claims provide a representative basis for determining the appropriate APC assignment for CPT 0563T and those limited claims could have been filed in error. This is particularly important because the current APC payment does not adequately recognize the resources required to furnish the procedure in the HOPD and may create a barrier for providers seeking to offer TearCare to Medicare beneficiaries in other settings of care.

AAO, ASCRS, ASRS, SEE and OOSS believe that CPT 0563 should be reassigned to *APC 5503, Level 3 Extraocular, Repair and Plastic Eye Procedures,* which is a more clinically appropriate and resource-homogeneous APC. The CY 2027 proposed payment for APC 5503 is approximately $2,808. APC 5503 includes therapeutic ophthalmic procedures involving the eyelid, ocular surface, cornea and lacrimal system, including procedures requiring specialized ophthalmic technology and direct physician intervention.

PAYMENT FOR SKIN SUBSTITUTES

Our organizations appreciate the agency's efforts to reduce skin substitute costs across sites of care in 2027 and beyond. We are also encouraged by the inclusion of non-sheet skin substitute products in payment rates, coding, and coverage, including the newly established G-codes. Because non-sheet products—including powders, gels, ointments, foams, liquids, and injected products—serve the same or similar clinical purposes as sheet versions and are derived from the same source material, ensuring similar payment rates as sheet products recognizes their shared clinical value, avoids artificial distinctions based on form factor, and preserves physician flexibility to select the formulation best suited to each patient.

Payment parity also supports innovation by encouraging investment in alternative ophthalmic delivery formats that may improve efficiency, ease of use, or patient tolerability. Treating non-sheet formulations comparably to sheet products helps ensure new ophthalmic technologies would also be evaluated on therapeutic value rather than disadvantaged by coding or reimbursement policy.

NEW TECHNOLOGY INTRAOCULAR LENSES (NTIOL)

CMS should promote innovation and ensure that Medicare beneficiaries have access to critical, life-saving new cures and technologies that improve beneficiary health outcomes. This should apply to all emerging technologies, including New Technology Intraocular Lenses (NTIOLs), which replace a beneficiary's natural lens that has been removed during a cataract surgery. Since 1999, when CMS established the additional payment rate for a new NTIOL at $50 per lens, there has not been a payment adjustment, despite major technological advances in IOLs over the last two decades. There continue to be unmet needs for post-cataract patients, including enhancing lens quality, reducing the need for secondary interventions, and addressing negative dysphotopsia.

In real dollar terms, the flat rate payment for NTIOLs has significantly lagged the overall economic inflation rate and is not reflective of the increased costs associated with research and development to bring new technologies to market. When the NTIOL provisions were established more than two decades ago, CMS stated it would revisit the appropriateness of the fee established for cataract surgery with IOL insertion when a lens determined to be an NTIOL is furnished. Now is an appropriate time to make such an adjustment. The IOL industry continues to advance ocular innovation with new monofocal IOL technologies. These future IOLs have the potential to provide meaningful outcomes for cataract patients.

To meet CMS' original objectives to enable Medicare beneficiaries' quick access to new technologies, we strongly encourage CMS to consider increasing the per lens payment from $50 to $100 in CY 2027. Additionally, we request that the NTIOL payment be updated annually to allow Medicare beneficiaries to have access to future innovation.

In conversations with CMS representatives, we have learned that there are currently no active classes of NTIOLs. As such, since 2011, stakeholders have submitted information to be approved as astigmatism-correcting and/or presbyopia-correcting *instead of* pursuing NTIOL status which could be made available to more beneficiaries. To foster innovation and support patient access to modern, rapidly evolving technologies, we propose that CMS publish annually a list of active NTIOL classes. The publication of active NTIOL classes will allow new applications to be accepted and catalyze a reemergence of participation within this program across multiple companies within industry.

UNLISTED CODES

A significant anomaly in CMS' effort to align the ASC and HOPD payment system is the treatment of procedures for which there is not an appropriate CPT code. In some ASCs, surgeons utilize innovative techniques or new technologies to perform a procedure; this can mean that the service is not described by a specific CPT code. These services are reimbursed in the HOPD (and, indeed, in physician offices) but are not eligible for payment in the ASC. In the proposed 2008 ASC payment rule, CMS stated that, without knowledge of the procedure's code, it cannot determine whether the procedure performed would have been excluded from the ASC payment under the rule's safety criteria.

Although an unlisted code does not allow the reporting of specific procedures, the code does include the narrowly defined anatomic region of the service that could provide the basis for

a determination about the safety of the procedure in the ASC. There is no clearly stated safety rationale for this policy. Commercial insurers typically afford ASCs the flexibility to use unlisted CPT codes to make claims for payment. We note that the agency does permit HOPDs and even physician offices to use unlisted codes; allowing this practice for ASCs will enable CMS to derive savings for both the program and beneficiaries. If physicians are permitted to choose to perform a procedure with an unlisted code in HOPDs, facilities that are managed, staffed, and equipped like Medicare-certified ASCs, surgeons should be allowed to utilize unlisted codes in the ASC. **We urge CMS to revise the Federal Code of Regulations to eliminate this restriction on billing in ASCs with unlisted codes.**

HOPD PRIOR AUTHORIZATION EXPANSION

CMS proposes to incorporate additional codes into the existing botulinum toxin injections service category that is subject to prior authorization in the HOPD setting beginning July 1, 2027. The proposed additions are:

- 64611, Chemodenervation of parotid and submandibular salivary glands, bilateral
- 64616, Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
- 64617, Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed
- 64642, Chemodenervation of one extremity; 1-4 muscle(s)
- 64644, Chemodenervation of one extremity; 5 or more muscles
- 64646, Chemodenervation of trunk muscle(s); 1-5 muscle(s)
- 64647, Chemodenervation of trunk muscle(s); 6 or more muscles
- J0589, Injection, daxibotulinumtoxina-lanm, 1 unit

While the specific code additions may have limited impact for ophthalmologists, we remain deeply concerned by the plan to expand the HOPD prior authorization program when longstanding, unresolved problems with the existing HOPD program as it applies to ophthalmology-related botulinum toxin injections and eyelid/brow procedures remain unaddressed. Since the HOPD program was implemented, the Academy, American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS), North American Neuro-Ophthalmology Society, and Outpatient Ophthalmic Surgery Society have repeatedly raised concerns that prior authorization requirements have led to improper denials, unnecessary requests for additional information, and delayed access to medically necessary care. Although CMS is separately operating a related ASC Prior Authorization Demonstration for certain overlapping ophthalmology-related services, our comments here focus on the HOPD program and the need for CMS to correct these problems before further expanding prior authorization.

The Existing HOPD Prior Authorization Program Has Unresolved, Longstanding Operational Problems

Since 2021, ophthalmic plastic and reconstructive surgeons nationally have reported confusing and improper prior authorization denials of medically necessary botulinum toxin injections to the periocular facial muscles (orbicularis, corrugator, procerus, and glabella), despite the fact that these injections have been the accepted standard of care for treatment of blepharospasm and hemifacial spasm for more than 40 years. Through direct communication with the Medicare Administrative Contractors (MACs), it became apparent that the prior authorization program itself prompted this shift in coverage: in an effort to formulate medical necessity criteria for prior authorization, MAC medical directors adopted a literal, overly restrictive interpretation of decades-old FDA-label dosing instructions for onabotulinumtoxinA. For more than five years, the ophthalmology community has worked with the MACs to clarify clinical guidelines and to restore their longstanding application of the recognized off-label exception for onabotulinumtoxinA, with limited success to date.

Ophthalmologists performing ptosis repair have separately experienced inappropriate delays in authorization when a MAC reviewer requests justification for an anterior versus posterior surgical approach. So long as medical necessity for the procedure itself is documented, the choice of surgical technique is a matter for the surgeon and patient, not a medical reviewer, and these requests for additional information create administrative burden and delay care without a corresponding clinical benefit.

Because these operational problems with the existing HOPD prior authorization program remain unresolved after several years of engagement, we urge CMS to prioritize fixing them — including by directing MACs to apply clinically appropriate, updated coverage criteria for onabotulinumtoxinA and to refrain from challenging documented, medically necessary surgical technique choices — before further expanding the program's reach.

CMS Has Not Substantiated the Basis for Prior Authorization of These Services

CMS’s rationale for subjecting ophthalmology-related botulinum toxin injections and eyelid/brow procedures to prior authorization in the HOPD setting centers on preventing improper or fraudulent payments for services that could potentially be billed as cosmetic rather than medically necessary. However, CMS has not published audit data or other evidence substantiating that fraud, waste, or abuse is prevalent among these HOPD services. Our organizations share CMS’s interest in preventing improper billing and have long worked to educate our members on correct coding, but we are not aware of evidence supporting the premise that these HOPD procedures pose an elevated fraud risk warranting prior authorization.

Claims data also underscore the need for CMS to justify the scope of the HOPD prior authorization program with setting-specific evidence. The ophthalmology-related services at issue are low-volume services overall, and many are furnished predominantly outside the HOPD setting. Subjecting low-volume, medically necessary services to HOPD prior authorization imposes administrative costs on providers, facilities, patients, and CMS’s contractors that may be disproportionate to any demonstrated program-integrity benefit. also caution CMS against treating site-of-service shifts observed after HOPD prior authorization took

effect as evidence that these services are inappropriate or fraudulent when furnished in other settings. It was entirely foreseeable that physicians would shift services away from the HOPD when doing so was clinically appropriate and less administratively burdensome; that rational response does not establish that HOPD prior authorization is justified or that further expansion is warranted.

CMS Has Consistently Underestimated the Administrative Burden of Prior Authorization Programs

CMS's administrative burden estimates materially understate the real-world time and staffing costs of prior authorization. The American Medical Association's 2025 prior authorization physician survey found that physicians and their staff spend 13 hours each week completing prior authorizations, diverting resources from patient care.[1] Ophthalmology practices and HOPDs face the same documentation, submission, follow-up, and appeals burdens, which are especially difficult for small and rural practices and facilities with limited administrative capacity.

The burden also affects patients. Prior authorization delays can postpone medically necessary treatment for blepharospasm, hemifacial spasm, and visually significant upper eyelid disease, conditions that can impair driving, reading, work, and other daily activities. CMS should account for these patient access consequences before expanding HOPD prior authorization to additional services.

Recommendations

For the reasons detailed above, we do not support expansion of the HOPD prior authorization program until CMS resolves the program's existing operational and evidentiary problems in the HOPD setting. With respect to this proposed rule, we ask CMS to:

- Resolve the documented, unresolved operational problems with the existing HOPD prior authorization program for ophthalmology-related botulinum toxin and eyelid/brow procedures before finalizing any further expansion of the program;

- Direct MACs to apply clinically appropriate, updated medical necessity criteria for onabotulinumtoxinA consistent with more than 40 years of accepted clinical practice, and to cease requesting justification for a surgeon's choice of surgical technique (e.g., anterior versus posterior ptosis repair) once medical necessity for the underlying procedure is documented. MACs should not rely on out of date FDA-labels.;

- Publish the audit data or other evidence supporting CMS's stated concern that ophthalmology-related botulinum toxin and eyelid/brow procedures are being billed fraudulently in the HOPD setting, and reassess the inclusion of these codes in the HOPD program in light of the limited claims volume and significant administrative burden associated with prior authorization; and

- Commit to periodic reassessment, in consultation with the Academy and interested ophthalmic subspecialty societies of whether continued prior authorization for these low-volume, low-fraud-incidence, high clinical-value services remains warranted.

Our organizations remain available to work with CMS to correct the HOPD prior authorization program issues and to ensure that any program-integrity policies affecting ophthalmology services are evidence-based, clinically appropriate, and administratively feasible.

Interim Software as a Medical Service (SaMS) Reimbursement Policy

For CY 2027, CMS proposes to designate several codes across specialties as SaMS technologies and reassign them into New Technology APCs under the new status indicator "O1." In ophthalmology, this includes CPT code 92229, which CMS proposes to move from APC 5733 (status indicator "S") to APC 1502, at a proposed rate of $75.50 compared with $66.91 under the prior assignment.

Our organizations appreciate CMS's efforts to identify a workable, near-term solution for adequate reimbursement of novel, software-based technologies. Services like CPT 92229 do not fit neatly into the reimbursement structures, and we recognize the genuine difficulty of building a payment methodology for an emerging category of services in a system designed decades ago. We are glad to see CMS now engaging with this challenge directly, including through the comment solicitation addressed below, rather than leaving these services in an undefined status.

We appreciate that CMS's proposal would, in the instance of CPT 92229, increase payment for the affected service relative to its current clinical APC assignment, and more broadly appreciates CMS's willingness to use its equitable adjustment authority to keep an array of novel software-based services separately and adequately paid while a permanent methodology is developed, rather than allowing payment for these technologies to lag behind their adoption in clinical practice.

Our organizations believe status indicator "O1" could serve as a reasonable, temporary bridge for SaMS technologies while CMS develops a permanent payment methodology for these services, but only if CMS implements the new indicator correctly and unambiguously, particularly with respect to how multiple procedure discounting applies.

That is not a minor technical point. SaMS services are often furnished alongside other separately payable services during the same patient encounter. If status indicator "O1" is implemented, applied, or understood by hospital billing systems, Medicare Administrative Contractors (MACs), and other payers as subject to multiple procedure discounting, even inadvertently, through ambiguity in how the indicator is defined, beneficiaries could effectively lose reliable access to these services. We therefore urge CMS to state explicitly, in the final rule and Addendum D1 definition of status indicator "O1" itself, that "O1" carries the same "not discounted when multiple" payment treatment as status indicator "S."

Because this is a new and still-developing payment framework with consequences that reach well beyond any single code or specialty, we ask that CMS provide additional clarity on the following aspects of the interim SaMS reimbursement framework in the final rule:

- **Long-term payment methodology**. CMS describes this as an interim policy pending a more comprehensive, permanent SaMS payment methodology. We ask that CMS commit

to a timeline for developing that methodology and to using notice-and-comment rulemaking, rather than sub-regulatory guidance, to establish it.

- **Movement into and out of the New Technology APC**. We ask CMS to articulate clear, objective, and transparent criteria for when a SaMS code will move out of a New Technology APC and back into a clinical APC (or vice versa), so that reassignment decisions do not appear ad hoc to the specialties and technologies affected.

ASC QUALITY REPORTING PROGRAM

AAO, ASCRS, ASRS, OOSS and SEE appreciate the efforts undertaken by CMS to implement the ASC Quality Reporting Program over the years and the agency's acceptance of many of the suggestions proffered by our organizations. Accommodating the perspectives and concerns of the ASC and surgical communities is undoubtedly a major factor in the exceptional 98-plus percent reporting rate by facilities with respect to measures implemented to date. We believe that the following are prerequisites to the adoption of a quality measure for the ASC. A measure should:

- Relate specifically to the episode of care in the ASC;
- Evaluate the practices and quality of the care provided in the facility;
- Involve reporting by the facility of data available in the ASC chart;
- Produce outcomes data that is actionable by the ASC, embodying the potential to improve the quality of care provided in the facility; and,
- Have been tested in the ASC environment.

ASC-11 Should Be Permanently Withdrawn as an ASC Quality Measure.

Since the publication of the 2014 ASC payment rule, our organizations have strenuously objected to the application of Measure ASC-11: *Cataracts – Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery.* We applauded the agency's decision several years ago to withdraw the measure for mandatory reporting by facilities and were disappointed that this measure, misguided in its application to the ASC, was included in the 2022 final payment rule.

NQF 1536, from which the measure is derived, is a patient-reported outcome measure taken singularly from a measure group designed for registry-only reporting by physicians and was never intended to serve as a measure of facility-level quality and has never been tested for facility reporting. The bedrock foundation of quality reporting in the ASC is that facility-level measures should relate to *an episode of care that occurs within the confines of the ASC, encompass data that is available within the ASC chart, be collectable by ASC staff, generate conclusions that are actionable by the facility, and have been tested in the ASC environment.*

ASC-11 meets none of these criteria. For the reasons stated herein, we are not surprised that only a few dozen facilities have opted to report on ASC-11 on a voluntary basis, and, therefore, sparsely reported results could not possibly result in a sufficiently meaningful sampling in terms of measuring ASC quality, either on a facility-by-facility or industry-wide basis. **While we support the agency's recent decision to keep reporting of ASC-11 voluntary through at**

least the 2031 payment determination year, our organizations strongly believe that ASC-11 should be withdrawn from the program altogether.

CMS Should Adopt a Quality Measure for TASS

In 2018, CMS invited public comment regarding the adoption of a measure, developed by the ASC Quality Collaboration, to assess the number of patients diagnosed with Toxic Anterior Segment Syndrome (TASS) within two days of undergoing anterior segment surgery in the ASC. The measure was reviewed by the Measures Applications Partnership seven years ago and received conditional support pending endorsement by the National Quality Forum (NQF). CMS did not finalize adoption of this measure in the 2018 rulemaking.

TASS, an acute and serious inflammation of the anterior chamber, or segment, of the eye following cataract surgery, is directly related to extraocular substances that inadvertently enter the eye during surgery. There are published guidelines regarding cleaning and sterilization of intraocular surgical instruments to help improve quality and prevent TASS. This measure would promote collaboration between the surgeon and the facility, as the surgeon, under current practice, would report back to the facility any incidence of TASS. Further, measuring the incidence may aid in better tracking and understanding of the prevalence of TASS, as the Food and Drug Administration contends that TASS is significantly under-reported, and surveillance is underway. Specific prevention guidelines have been developed, and this measure would help ensure that those cases are being followed appropriately. **AAO, ASCRS, ASRS, OOSS, and SEE strongly support inclusion of the TASS measure in the ASCQR program**.

Reprieve From Penalties for ASCs That Encountered Issues Achieving 200 completed OAS CAHPS Surveys

As we stated last year, compliance with the OAS CAHPS mandate has proven to be a significant challenge. The requirement that facilities contract with a CMS-approved vendor to conduct surveys has imposed a significant time and cost burden on our member ASCs. We believe that many facilities, despite having undertaken the tasks to implement the program, will be unable to meet the requirement of 200 completed surveys. **We recommend that if a facility is operational with the OAS CAHPS survey, it not be penalized if fewer than 200 patients complete the survey.**

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Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2027 Medicare ASC payment rates and the ASC Quality Reporting Program. Should you have any questions or require further information, please feel free to contact us at: Brandy Keys, Director of Health Policy, AAO, bkeys@aao.org, 202.737.6662; Mark Cribben, Director of Government Affairs, ASCRS, mcribben@ASCRS.org, 703.591.2220; Allison Madson, Vice President of Health Policy, ASRS, allison.madson@asrs.org, 312.578.8760; Michael Romansky, JD, Washington Counsel, OOSS, mromansky@OOSS.org, 301.332.6474; and, Allison Shuren, JD, Washington Counsel, SEE, allison.shuren@aporter.com, 202.942.6525.

We appreciate your consideration of our views.

American Academy of Ophthalmology
American Society of Cataract and Refractive Surgery
American Society of Retina Specialists
Outpatient Ophthalmic Surgery Society
Society for Excellence in Eyecare