September 15, 2025

The Honorable Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services Department of Health and Human Services
Attention: CMS-1834-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-1834-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 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 ambulatory surgical center (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 2026 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 2026. We strongly believe that it should be adopted permanently. We will discuss below other payment policy changes that should ameliorate some of the distortions in relative payments to ASCs and HOPDs.

Since CMS decided almost 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

- **CMS should clarify and disclose what, if any, costs were discounted on the 66984 claims that would have led to a lower geometric mean cost for the same set of rate-setting claims. If CMS did make a change to the rate-setting methodology and did not address it in the proposed rule documents, we urge CMS to hold off on any changes until the details are made available through rulemaking for public comment.**

- **CMS should refrain from applying the secondary rescalar to the ASC payment system and, instead, combine the OPPS and ASC utilization and case mixes to establish a single weight rescalar.**

- **We applaud the agency's decision to maintain the HMB as the ASC update factor through 2026. 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.**

- **Retinal detachment repair is reimbursed well-below the cost 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 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.**

- **CMS should finalize the assignment of CPT codes 66989, 66991, and 0671T to APC 5493.**

- **CMS should finalize device-intensive designation for CPT codes 66989, 66991, and 0671T for CY 2026, and determine the ASC payment rate for these codes accordingly**.

- **CMS should adhere to its own policy per the Medicare Claims Processing Manual, Chapter 4, Section 20.6.4 and continue assigning a default device offset percentage of at least 31 percent to CPT 0621T and reinstate the correct ASC payment indicator "J8" until valid claims data for 0621T are available.**

- **CMS should establish a drug-intensive policy for ASC rate setting along the lines of the current device-intensive policy.**

- **CMS should (1) assign CPT code 68841 to APC 5503 with a different status indicator that allows for separate payment in the ASC setting (e.g., "J1") and (2) treat Dextenza as a non-opioid treatment for pain relief and use of the current methodology to calculate the CY 2026 payment limit.**

- **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).**

- **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 2026.**

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

- **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 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 BENEFICIARY

As discussed in detail below, we are extremely disappointed that CMS continues to use a secondary rescalar to budget-neutralize ASC facility payments. This, coupled with what our organizations believe is a miscalculation of cataract surgery facility payments by CMS, results in a 4.7 percent 2026 decrease in cataract surgery facility fees (CPT 66982 & CPT 66984).

The items and services encompassed in the ophthalmic surgery centers' facility fee include:

- Nursing services and services of technical personnel
- Use by the patient of ASC facilities including the operating room and recovery room
- Drugs, including take home medications, surgical dressings, and supplies
- Diagnostic or therapeutic items and services directly related to the procedure
- Administrative, record keeping and housekeeping items and services
- Materials for anesthesia, and
- Intraocular lenses.

In this time of inflation, our members note that virtually all of these costs referenced above have increased, and in some instances, substantially so. A reduction of 4.7 percent in reimbursement makes absolutely no sense.

In formulating ASC policy and establishing payment rates, it is imperative that the agency recognize that most ASCs are small businesses that must run efficiently to remain in operation. There are over 6,000 Medicare-certified ASCs – about 1,200 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. (We note that 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 rescalar 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 .

Under the proposed rule, facility payment for cataract surgery with IOL (66984) in 2026 would be $1,156 (reduced from $1,205 in 2025) in the ASC setting, while reimbursement for the same procedure in the HOPD would be $2,275. The beneficiary's financial obligation in the form of copayments would be $231 in the ASC and at least $455 in the HOPD; patient cost-sharing is always lower in the ASC. Therefore, for each cataract operation performed in an ASC instead of an HOPD, the program would save $835 and the beneficiary $231 for a savings of $1,066 or more. With about 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 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 2026 proposed rule and the possible miscalculation of the ASC base rate for cataract, as well as the recent reclassification 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.

Miscalculation of Geometric Mean Costs in Establishing Cataract Surgery Facility Fee

In the HOPD, CMS is proposing a $97 (4 percent) decrease in the payment rate for APC 5491, Level 1 Intraocular Procedures. The procedure code with the vast majority of the single claims volume in APC 5491 is CPT 66984, *Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*; therefore, this decrease is likely attributed to the reported decrease in the geometric mean cost of CPT 66984. Due to the secondary weight scalar, the decrease to reimbursement is compounded in the ASC setting, where most cataract surgeries are performed. Under the proposed rule, ASC facility payment for CPT 66984 in 2026 would drop by $56 (4.7 percent).

Many of our organizations' members have shared concerns that the reported decrease in the geometric mean cost of CPT 66984 does not align with the experiences of their practices and ASCs and that a cut to cataract surgery reimbursement may make it challenging to provide the service. In response to this feedback, AAO engaged McDermott Plus (M+) to investigate the OPPS rate setting claims for CPT 66984. M+ calculated the procedure level geometric mean cost using the OPPS CY 2026 rate-setting file released with the proposed rule, which consists of CY 2024 claims data. To confirm the accuracy of their calculation, M+ also replicated the CY 2025 final rule procedure level geometric mean costs, utilizing CY 2023 claims data. For both rule years, M+ utilized the corresponding OPPS rate-setting file released by CMS.

M+ was able to match the single frequency count and geometric mean cost for 66984 published in the CPT Cost Statistics file released with the OPPS CY 2025 final rule. However, when the exact same approach with updated input files was used for the CY 2026 Proposed Rule, M+ matches the single claim counts but calculates a geometric mean cost 9% greater than CMS

(see Table 1).

Table 1. Comparison of CMS and M+ Results for 66984 OPPS Rate-setting

	Addendum B			CMS Cost Statistics File			M+ Replication Model		Comparison	
Rule Year	SI	APC	Pay Rate	Singles	Total	GMC	M+ Singles	M+ GMC	% Diff Singles	% Diff GMC
CY2025F	J1	5491	$2,280.73	247,327	249,477	$2,267.47	247,373	$2,267.94	**0.0%**	**0.0%**
CY2026P	J1	5491	$2,183.90	217,828	219,418	$2,167.01	217,751	$2,359.06	**0.0%**	**8.9%**

(Source: M+ analysis of CY2025F and CY2026P OPPS rate-setting files. GMC Geometric Mean Cost)

The APC 5491 payment rate using a 66984 geometric mean cost of $2,359 instead of $2,167 would be $2,352.55, an increase of 3% from CY 2025 (see Table 2).

Table 2. Comparison of APC Geometric Mean Cost and Payment Rate, CMS vs M+

	GMC 66984	GMC APC 5491	Payment Rate APC 5491 CY 2026 PR	Payment Rate APC 5491 CY 2025 FR	% Difference in Payment Rate CY25 to CY26
CMS	$2,167.01	$2,217.91	$2,183.90	$2,280.73	-4%
M+	$2,359.06	$2,389.19	$2,352.55	$2,280.73	3%

(Source: M+ analysis of CY2025F and CY2026P OPPS rate-setting files. GMC stands for Geometric Mean Cost)

Considering this inconsistency, our organizations respectfully ask CMS to clarify and disclose what, if any, costs were discounted on the 66984 claims that would have led to a lower geometric mean cost for the same set of rate-setting claims. There was no discussion in the OPPS CY 2026 proposed rule text preamble or the Claims Accounting document that mentioned new cost discounts specific to cataract procedures or supplies. If CMS did make a change to the rate-setting methodology and did not address it in the proposed rule documents, we urge CMS to hold off on any changes until the details are made available through rulemaking for public comment.

Rescaling Adjustment Applied to ASC Relative Weights

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 percentage has dropped to 65 percent; under the proposed 2026 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 rescalar and 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."

It is important to note that 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 suggests that the application of the rescalar in the ASC environment will continue to erode the relationship between ASC and HOPD payments*. The agency is needlessly increasing Medicare program costs by making it financially impracticable to furnish these services that are clinically appropriate for the ASC, and, hence, pressing physicians to perform these procedures to the more expensive HOPD setting. **We strongly recommend that the agency discontinue use of the rescalar**, which penalizes care in the most efficient 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 rescalar.

Our organizations realize that the elimination of the ASC weight rescalar 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 rescalar to the ASC payment system and, instead, combine the OPPS and ASC utilization and case mixes to establish a single weight rescalar.** By incorporating the ASC volume into OPPS weight rescalar 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 rescalar and whether such factors should or should not be offset in the ASC setting.

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 Hospital Market Basket (HMB) at least through 2026. 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 rescalar, 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 2026, 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 already 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

We are concerned about a growing national trend of reduced ASC access for retina surgery. According to ASRS's 2025 Preferences and Trends (PAT) survey, of 889 retina specialists responding, more than 71% of report difficulty accessing sufficient OR time, particularly for emergent cases such as retinal detachment repair. (Hahn P, ed. ASRS 2025 Preferences and Trends Membership Survey. Chicago, IL. American Society of Retina Specialists; 2025) Many retina specialists report either having their ASC surgical block time reduced or eliminated completely. For patients suffering these potentially-blinding conditions, the longer they have to wait for surgery the more likely they are to have a poor outcome.

Inadequate facility reimbursement is the main cause of reduced access for these surgeries. For retinal detachment repair (67108) and complex retinal detachment repair (67113), the geometric mean costs for each are higher than the reimbursement for the APC group in which key procedures are placed (Level 2 and 3 Intraocular procedures, respectively). The table below shows the significant loss each procedure is for a facility.

CPT Code	2026 Proposed OPPS Geometric Mean	2026 APC Payment	2026 OPPS Loss	2025 OPPS Geometric Mean	2025 APC Payment	2025 OPPS Loss
67108	$4,968.13	$4,309.45	$658.68	$4711.62	$4144.83	$566.79
67113	$5,731.53	$5,469.68	$261.85	$5554.54	$5333.89	$220.65

The above figures are OPPS rates, but also represent a loss for ASC payment. In addition, the table released as an addendum to the proposed rule appears to miscalculate the geometric mean for both level 2 and level 3 intraocular procedures. We request CMS recalculate these levels in the final rule.

Facilities cannot afford to allocate enough time to meet the patient demand when they are losing several hundred dollars on each case. Furthermore, as the above figures represent averages, many cases cost more. The time it takes to complete these procedures can be unpredictable as they are emergency surgeries that may require different surgical techniques, such as scleral buckling. A recent study from Blumenthal J, et. al. Operative Times in Scleral Buckle Surgery: Influencing Factors and Cost Analysis. *J Vitreoretin Dis*. 2024;9(1):18-25., found that scleral buckling in particular adds time to the case and cost. With a mean cost per case of $7674.64—a $2713.64 loss compared to Medicare payment of $4961. The same study also gathered data from numerous previous studies showing almost no uniformity in the time for scleral buckling or pars plana vitrectomy, another widely-used surgical technique. In practice, this means ASCs have to be selective in the cases and surgeons they accept—as in the case of a large retina practice in Maryland who has had their ability to operate in a local ASC limited to certain surgeons and procedures.

Logistically, the emergent nature of these cases and unpredictable operative times also make them more challenging for facilities to accommodate than more predictable, elective cases. Without advance notice, ASCs must deviate from the day's planned cases and modify the set-up for these retinal surgeries. This disrupts the ASCs' flow, and leaves other previously-scheduled patients waiting. Facing these realities, many ASCs have had to limit the number of retina cases they take or suspend the service entirely. Still others may continue to allocate block time to retina specialists, but cancel it if it is not fully scheduled ahead of time, such as a week prior, effectively cutting off access for any emergency cases.

This creates an undesirable situation for both patients and retina specialists. Public health is at risk when patients who need emergency surgery are often forced to travel long distances for care in larger, tertiary or academic medical centers. Retina specialists, in turn, cannot care for their patients in their preferred community-based settings. Retina specialists are then frequently put in the difficult position of finding a facility to accept the patient. A retina specialist in Southern California notes that only one local hospital accepts Medicaid patients, but no longer takes retina cases. Similarly, in Northern California an ASCs is in an unsustainable situation of

having to care for retina patients at a loss because there is no capacity at the local hospitals.

Not only are ophthalmic ASCs more cost-effective for patients and Medicare, they are also staffed by professionals who are trained to provide ophthalmic care and can best support retina specialists as they perform these delicate procedures—all leading to the best possible outcome for the patient. Academic centers also provide excellent care, but they are often themselves overwhelmed and are providing retina procedures at a loss. Studies from Haliyur R., et.al., Cost drivers of pars plana vitrectomy for retinal detachment: time-driven activity-based costing analysis. *J Vitreoretin Dis*. 2025;9(1): 11-17; Hwang MW, et.al., Time-drive activity-based cost analysis of pars plana vitrectomy in rhegmatogenous retinal detachment at a large academic center. *J Vitreoretin Dis*. 2025;9(1):26-30; and Berkowitz, ST, et.al., Cost analysis of routine vitrectomy surgery. *Ophthalmol Retina.* 2021;5(6):496-502 are among several recent studies that demonstrate the losses.

We recognize CMS wants care provided in the most cost-effective setting, but without updates to ASC payment for retina procedures, these cases will continue to move to higher-cost settings and patients will face longer waits and poorer outcomes. **We ask for CMS's assistance in addressing this access challenge in a way that adequately reimburses facilities for the costs of providing retina surgery and does not have the unintended consequence of reducing access for other ophthalmic surgery.**

COVERAGE OF NON-OPIOID DRUGS

To date, CMS is paying 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 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.

We appreciate that CMS solicited comments in 2023 regarding whether the agency should rely on factors other than FDA-approved indications labeling in its process for determining whether a drug qualifies as a non-opioid pain management drug. *Our organizations believe that, in future rulemakings, CMS should consider recommendations of specialty societies or other*

national organizations such as medical compendia developers as an alternative to the criterion based on the FDA labeling. Specialty societies and other clinical experts already play a key role in identifying clinically recognized uses for drugs that extend beyond FDA-approved labeling. It is important to consider an alternative criterion as the guidelines contained in medical compendia are continually evolving as clinicians identify new uses for existing drugs and these uses are empirically tested by scientists and clinicians.

We 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.**

FACILITY PAYMENT FOR MIGS AND OTHER INTRAOCULAR PROCEDURES

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 2026 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 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 payment rates' adequacy. Designating CPT codes 66989, 66991 and 0671T as device-intensive is necessary to achieve this objective. **Therefore, we recommend that CMS finalize device-intensive designation for CPT codes 66989, 66991, and 0671T for CY 2026, and determine the ASC payment rate for these codes accordingly**.

Another treatment for glaucoma involves the insertion of an intracameral sustained release micro-invasive intraocular implant inserted through the anatomical drain of the eye (i.e., the trabecular meshwork) and anchored in the sclera. This procedure for the insertion of a drug (travoprost) is reported using CPT codes 0660T and 0661T, with the latter procedure utilized when an implant is removed and another is inserted, while the former code is for the insertion of the implant. These codes were first payable under OPPS as of April 1, 2024, when CMS assigned the codes to APC 5492 for 2024. For CY 2026, CMS proposes to continue to assign both codes to APC 5492. As the claims data for these codes is not yet established, we agree with the proposed APC assignments and recommend that CMS finalize these proposals.

PAYMENT FOR TRABECULOSTOMY AB INTERNO BY LASER (CPT 0621T)

As established by the AMA CPT Editorial Panel with an effective date of January 1, 2021, CPT 0621T describes a novel glaucoma treatment procedure, trabeculostomy ab interno by laser (aka ELT). In February 2025, the AMA CPT Editorial Panel voted to retain CAT III status for CPT 0621T for another five (5) years, deeming it effective through December 31, 2030. This procedure requires a surgical incision through the cornea to enable the advancement of a single-use laser probe into the eye and placed in direct contact with the trabecular meshwork. While ELT has been performed effectively and safely in lowering intraocular pressure (IOP) in mild to moderate primary open angle glaucoma (POAG) patients in Europe for over ten years, to date, there are no FDA-approved or cleared devices in the United States capable of performing trabeculostomy ab interno by laser.

Data demonstrating its safety and effectiveness in treating POAG has been published in 20 peer reviewed publications to date, with publications as recent as August 2025: Moreno-Valladares, MD et al, *12-Month Intraocular Pressure and Hypotensive Medications Outcomes After Phaco-ELIOS Procedure–A Real World Study*, Journal of Glaucoma 34(8):p 585-590, August 2025 and 2022 by Berlin et al, *Eight-year follow up of excimer laser trabeculostomy alone and combined with phacoemulsification in patients with open-angle glaucoma*, J Cataract Refract Surg 2022; 48:838-843. Attached is a link to The American Academy of Ophthalmology's (AAO) website that provides a thorough clinical educational article describing the excimer laser trabeculostomy (ab interno) procedure – Excimer Laser Trabeculostomy: An Effective Microinvasive Glaucoma Surgery Procedure for Open-Angle Glaucoma - American Academy of Ophthalmology.

In the January 2019 update of the Hospital Outpatient Prospective Payment System (OPPS), CMS modified the device intensive criteria lowering the device offset criteria to be greater than 30 percent and to allow procedures that involve single-use devices, regardless of whether they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. Accordingly, effective January 1, 2019, all new procedures requiring the insertion of an implantable medical device will be assigned a default device offset percentage of at least 31 percent and thereby assigned device intensive status until claims data are available. In certain rare instances, CMS may temporarily assign a higher offset percentage if warranted by additional information. Considering this policy change, CMS modified the Medical Claims Processing Manual, chapter 4, section 20.6.4.

In the 2026 proposed rule, CMS has assigned a device offset of zero percent and zero dollars for CPT 0621T. As we commented with respect to the 2025 ASC proposal, we have significant concerns because CMS again does not explain how these values were assigned nor why it believes device intensive designation is no longer applicable.

Our organizations are aware that the Elios® System is currently undergoing two IRB-approved clinical trials in the United States, including a pivotal study designed to reduce intraocular pressure (IOP) in patients with Primary Open-Angle Glaucoma combined with cataract surgery. A second study evaluating the Elios® System as a standalone procedure received Medicare coverage as a Category B IDE study is ongoing. In CMS' 2025 OPPS/ASC

final rule, CMS reinstated the default device methodology to 0621T and assigned it with the appropriate ASC payment indicator of "J8" (device intensive procedure) with a default device offset of 31%.

Absent participation in the Category B IDE study, it was not possible for a hospital to submit a valid commercial claim reporting CPT 0621T in 2024. We believe the one claim shown in the 2026 NPRM OPPS "Two Times" Listing was done in error and should not be relied on to determine device intensive status for CPT 0621T in 2026. We have been informed by the manufacturer of the Elios® System that it anticipates receiving FDA approval in the first half of 2026. Removing device-intensive status for CPT 0621T would create a significant barrier to ASCs' ability to accommodate surgeons wanting to perform this procedure since the cost of the single-use, inserted device would no longer be accurately recognized in the ASC payment system. The unintended consequence of CMS' reliance on an erroneous claim would result in Medicare beneficiaries with glaucoma facing a barrier to needed innovation and new treatment options for this debilitating disease.

Our organizations strongly recommend that CMS adhere to its own policy per the Medicare Claims Processing Manual, Chapter 4, Section 20.6.4 and continue assigning a default device offset percentage of at least 31 percent to CPT 0621T and reinstate the correct ASC payment indicator "J8" until valid claims data for 0621T are available.

EXPIRING PASS-THROUGH DRUGS AND 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 58 of the Proposed Rule, CMS notes that over 30 drugs will have pass-through status expire on March 31, 2026, June 30, 2026, or September 30, 2026. CMS does not indicate how it will treat these products when pass-through status expires, leaving the health care community to ascertain 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, 2027, CMS should include in the CY 2027 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. 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 rightly has established a policy in the ASC rate setting process that allows the ASC rates to better reflect the 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 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 recommend that **CMS establish a drug-intensive policy for ASC rate setting, along the lines of the current device-intensive policy.**

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 significant disincentive to use Dextenza and requires beneficiaries to use alternatives such as eye drops. CMS's proposal also treats this procedure differently than the 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 64415, 66020, 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.

CMS proposes to continue separate payment for Dextenza as a non-opioid treatment for pain relief, finding that it meets the pertinent statutory criteria, and it proposes to utilize the same methodology for determining the payment limit for non-opioid treatments for pain relief. These proposals facilitate beneficiary access to non-opioid drugs, and we fully support CMS's efforts to provide physicians with increased tools to address pain without the use of opioids. Dextenza is a good example of how facilitating patient access to non-opioid medication to address pain and inflammation after surgery supports the potential to avoid compliance and safety problems stemming from the use of eye drops. Accordingly, CMS should finalize its proposals regarding drugs that qualify as non-opioid treatments for pain relief and the methodology for computing the payment limit for qualifying drugs.

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 in the ASC setting (e.g., "J1") and (2) treat Dextenza as a non-opioid treatment for pain relief and use of the current methodology to calculate the CY 2026 payment limit.

COVERAGE OF SKIN SUBSTITUTES

We appreciate the Agency's efforts to drive down the cost of skin substitutes across sites of care. AAO, ASCRS, ASRS, OOSS and SEE are also encouraged by the agency's request for information regarding the inclusion of non-sheet skin substitute products. **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).** By covering non-sheet offerings in a similar method to sheet products our organizations are hopeful innovations of skin substitutes will create new options for physicians to treat complex patients who require this type of product but may not tolerate a graft.

Our organizations support the Agency's proposal to codify in regulation that biological products approved by the FDA through the 351 BLA process are not skin substitute products, are excluded from the proposed incident-to payment, and will remain eligible for separate payment, including biological pathways for product coding and payment based on ASP. CMS has consistently and correctly stated in previous rulemaking that drugs and biologics regulated by the FDA under PHS 351 should continue to be eligible for separate payment under Section 1847A. In the CY 2023 Medicare Physician Fee Schedule proposed and final rules (CMS-1770-P and CMS-1770-F), the Agency noted that products approved by the FDA under Section 351 cannot be described as incident-to supplies. We respectfully request that the Agency codify in regulation that biologicals classified and approved by the FDA under Section 351 will be treated as biologicals under 1847A regardless of whether the Agency finalizes the proposal to treat non-biological skin substitutes as incident-to supplies. **Similarly, we ask the Agency to codify that these biologicals will be evaluated for coding and passthrough payment under CMS's drugs and biologics pathways and applications in the CY 2026 final rule.**

NEW TECHNOLOGY IOL (NTIOL) PAYMENT RATE

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 continues to be unmet needs for post-cataract patients, including enhancing lens quality, reducing the need for secondary interventions, and addressing negative dysphotopsia. In the final rule, our organizations request that the agency update the NTIOL payment rate of $50 to $100, which is reflective of the increase in the Consumer Price Index during the period 1999 to 2022.

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 2026. Additionally, we request that the NTIOL payment be updated annually to reflect CMS' decision to increase the NTIOL payment will help ensure Medicare beneficiaries have expanded 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 with unlisted codes.**

QUALITY REPORTING PROGRAM (QRP)

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 they are being followed appropriately. **AAO, ASCRS, ASRS, OOSS, and SEE strongly support inclusion of the TASS measure in the ASCQR program**.

Proposed Removal of ASCQR Measures

AAO, ASCRS, ASRS, OOSS, and SEE support the removal of *ASC-20: COVID -19 Vaccinations Coverage Among HCP* as well as the Health Equity Measures (ASC-22 through ASC-24) from 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 2026 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 much 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