



AMERICAN ACADEMY
OF OPHTHALMOLOGY®



September 13, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-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; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

We appreciate this opportunity to submit comments on behalf of five leading ophthalmology organizations with regard to CMS-1753-P, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating*. Collectively, the members of our societies are responsible for performing the vast majority of all ophthalmic surgical procedures performed in the US, most of which, 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 nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education 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 3,000 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. (ASCQC developed the claims-based quality measures incorporated within the recent rulemakings governing ASC quality reporting.)

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 2023 Medicare ambulatory surgical center (ASC) payment rates and the Quality Reporting Program for ASCs. Particularly with respect to the latter, we are very pleased that a number of the recommendations of the ASC and ophthalmology communities have been adopted in the recent past and appreciate the close collaboration among industry, medicine, and the agency that has characterized the development of the QR program. Most 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 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.

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 these savings.) Importantly, if volume migration continues at the same rate as 2011-2018, surgery centers are projected to save Medicare \$74.2 billion from 2019-2028. Policies that encourage migration embody the potential to generate even greater savings than those projected. Our comments reflect our organizations' commitment to providing the highest quality and most accessible care at lower cost to the Medicare program and its beneficiaries.

The nation's ophthalmic ASCs are committed to providing Medicare beneficiaries with access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the Medicare program in the containment of health expenditures. Since 1982, ASCs have expanded their role in meeting the surgical needs of the Medicare population and have done so saving billions of dollars annually. Simply stated, at a time when public policymakers are searching for meaningful health care reform -- improving quality and access, while reducing costs -- ASCs embody the potential to be a significant part of the solution. Despite CMS' decision in 2019 to change the ASC update factor from the CPI-U to the HMB, elements of the proposed regulation, particularly the use of the rescaler to achieve

budget neutrality, will continue to thwart, rather than enhance the ability of our facilities to continue to serve the nation's Medicare beneficiaries.

Under the proposed rule, facility payment for cataract removal Category I Current Procedural Terminology 66984 (CPT®) in 2023 would be \$1,080, while reimbursement for the same procedure in the HOPD would be \$2,183. The beneficiary's financial obligation in the form of copayments is \$216 in the ASC and at least \$437 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 and beneficiary save over \$1,103. With more than 1.8 million cataract surgery cases performed per 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, as confirmed now by a multitude of studies and reports, 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.

SUMMARY OF RECOMMENDATIONS

- ❖ **CMS should maintain use of the hospital market basket as the annual update mechanism for ASC payments.**
- ❖ **CMS should apply the OPPS relative weights to ASC services and discontinue the rescaling of ASC relative weights. Rescaling has had the effect of arbitrarily and inappropriately reducing ASC payment rates and causing a substantial divergence in payment rates between HOPDs and ASCs that is unrelated to the costs of delivering services in those settings**
- ❖ **CMS should develop a policy that covers all drugs that are administered at the time of cataract surgery, but are not integral or necessary to the cataract procedure, and have an FDA-approved indication to treat or prevent post-operative concerns, such as pain and inflammation (or, alternatively, indications reflected in specialty society guidelines or medical compendia) separately under Part B. Payment for drugs with expiring pass-through status should be extended through the Covid-19 public health emergency. Payment should also be extended to the HOPD setting.**
- ❖ **CMS should reassign the standalone MIGS procedure (CPT 0671T) to APC 5492.**
- ❖ **With respect to payment for Dextenza, CMS should assign CPT 68841 to APC 5503 with a J1 status indicator.**
- ❖ **With respect to insertable devices, CMS should use alternative measures to calculate the device-offset percentage when necessary to ensure fair payment to ASCs.**
- ❖ **CMS should adjust the New Technology IOL (NTIOL) payment rate from \$50 to \$86.49.**
- ❖ **CMS should assign the three artificial iris implantation codes (0616T, 0617T, and 0618T) to APC 5495 Level 5 Intraocular Procedures.**
- ❖ **CMS should permanently withdraw proposed Measure ASC-11 from the ASC Quality Reporting Program and establish a measure reporting on TASS.**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS implement by January 1, 2008, a new ASC payment system. Our organizations and the entire ambulatory surgery community reached consensus on the appropriate contours of an equitable and rational program. In the final ASC payment regulation that became effective in 2008, CMS adhered to the spirit, if not the letter, of many of these principles, most importantly, that the new payment system should be modeled on the methodology and payment rates applicable to surgical services furnished in HOPDs.

For well over a decade, we have expressed grave concerns that the continued use of the Consumer Price Index – Urban (CPI-U) rather than the HMB as the ASC update factor as well as maintenance of the rescaler to achieve budget neutrality will continue to exacerbate the gap between the ASC and HOPD payment rates in ways that were unrelated to comparable cost differences in the provision of care in the two settings, with respect to technology and staffing costs which are identical. **We appreciate that CMS has responded to some of our concerns, particularly taking the important step of replacing the CPI-U with the HMB as the annual update factor for ASCs (at least through 2023), a key step in encouraging additional procedures to be performed in the more cost-effective ASC. To ensure that this proposal has its intended effect, however, we recommend CMS also eliminate the secondary rescaler.**

In 2003, aggregate ASC payments as a percent of HOPD rates were 85 percent. When the new system was established in 2008, the percentage had dropped to 65 percent; under the proposed 2023 rates, Medicare will reimburse HOPDs, on average, 100 percent more than ASCs performing the same procedures. We note further that whereas ASCs accounted for 6.63 percent of total expenditures in 2016, the ASC percentage of that spend is declining, representing only 5.9 percent in 2022. This situation is the result of the application of the rescaler 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.

In formulating ASC policy and establishing payment rates, it is imperative that the agency recognizes 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 hospitals compromises the ability of our facilities to continue to provide the care and technology that Medicare beneficiaries deserve.

As discussed in greater detail below, the agency's continued utilization of rescaling to achieve budget neutrality in the 2023 proposal, 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, increase beneficiary out-of-pocket costs, and inhibit transparency regarding price and quality among Medicare providers, thereby jeopardizing beneficiary access to affordable, high quality surgical care.

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 to the proposed rule. With this spirit of cooperation and commitment to formulating a rational and equitable ASC paymentsystem, we join the ASC industry and other surgical specialty organizations in offering our specific comments:

ANNUAL PAYMENT UPDATE AND REQUEST FOR COST DATA

As we have emphasized in our comments in recent years, our organizations strongly support the agency's decision to change the ASC update factor from the CPI-U to the Hospital Market Basket (HMB). The CPI-U does not reflect ASC cost growth; the HMB is a better proxy for ASC cost increases. ASCs and HOPDs treat the same patients for the same conditions and 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 can potentially promote appropriate migration of services from the HOPD to ASC**, generating significant cost savings to the Medicare Program. ASC growth has been compromised by lack of parity in payment to HOPDs and ASCs. Aligning conversion factors – in addition to eliminating the rescaler, as discussed below – will equitably level the playing field between hospital and freestanding surgical facilities.

CMS has, in the proposed rule, again 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, however, CMS elects to collect data to establish a new 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 are aligned over time.** In developing a data collection modality, CMS should keep in mind that ASCs already incur excessive 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.

RESCALING ADJUSTMENT APPLIED TO ASC RELATIVE VALUE WEIGHTS

AAO, ASCRS, ASRS, OOSS, and SEE strongly believe that CMS should eliminate the rescaling of the ASC relative weights, as this practice has increasingly exacerbated the gap between ASC and HOPD payments and inappropriately reduced payments to ASCs without evidence of growing differences in capital and operating costs in the two settings. 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 OPSS relative weights, recent experience 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.* In 2016, the rescaler was 0.9332 and, in 2017, 0.9030; in 2018, the rescaler fell to .8995 for a 10.1 percent reduction to ASC weights. Under the proposed rule, the relative weight would be 0.8474 which, if implemented, would result in a 15.26 percent reduction in ASC weights. *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 rescaler 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 encouraging physicians to provide these procedures in the more expensive HOPD setting. **We strongly recommend that the agency discontinue the use of the rescaler.**

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 rescaler 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 the applying the secondary rescaler to the ASC payment system and, instead, combine the OPSS and ASC utilization and mixes in services to establish a single weight scaler.** By incorporating the ASC volume into OPSS weight scaler calculations, CMS would improve the alignment of the payment systems and more accurately scale for outpatient volume across both sites of service.

Now 15 years after the implementation of the ASC payment system, it is past time that CMS undertake an analysis of what is causing the rising trend in the OPSS rescaler and whether such factors should or should not be offset in the ASC setting.

COVERAGE OF NON-OPIOID DRUGS

We were pleased that CMS proposed to codify last year a modest expansion of its Non-Opioid Pain Management policy and solicit comments on several related implementation issues. To date, CMS is paying separately in the ASC for only a very limited number of specific 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 have an indication for the treatment of post-operative pain and/or inflammation and/or other sequela of the surgery. Our organizations believe that CMS should consider as part of future rulemakings to expand its proposed criteria for Non-Opioid Pain Management Drugs, in addition to the FDA label indication, to also recognize a drug as having pain management attributes when demonstrated based on the recommendation of recognized specialty societies, or guidelines contained in medical compendia.

AAO, ASCRS, OOSS, ASRS and SEE maintain that since these medications have a post-operative indication, they should not be considered surgical supplies bundled into the facility payment, but instead be covered and paid for under Medicare Part B, just as topical steroids and non-steroidals are paid under Part D. ASCs face the same challenges in affording to provide these drugs as they do to provide the specific non-opioid pain management drugs -- Omidria and Dextenza are the only ophthalmic drug encompassed by existing policy for payment of non-opioid drugs -- that CMS removed from the facility fee for that reason. The problem is compounded by the reality that ASCs are receiving, as discussed in detail above, only half of the reimbursement provided to HOPDs.

Medications administered during surgery are intended to replace some, or all, of the eye drops patients must administer to themselves post-procedure and that are covered and reimbursed separately under Medicare Part D. Many ophthalmic surgery patients are aged and have memory limitations, significant physical limitations that make drop instillation difficult or impossible, and comorbidities. These medications are a valuable treatment alternative to post-op drops and have the potential to improve patient outcomes by reducing or eliminating the need for patient-administered post-operative medication. Because they have an FDA-approved post-operative indication, these drugs are unique and have benefits well beyond traditional surgical supplies.

Dexamethasone is a drug commonly used in ophthalmology because of longstanding evidence that it reduces inflammation, and therefore, pain following cataract surgery. Some drugs that have the active ingredient dexamethasone, such as Dextenza, are already indicated for both 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.

Several companies are pursuing costly research and development of products that can deliver the medications necessary during the extended post-procedure period, including intracameral antibiotics that would be administered at the time of the ophthalmic surgery. Current policy will impede the development of these important pharmaceutical products. Without the assurance that ASCs will be able to afford to provide these treatments to patients, manufacturers will inevitably discontinue their innovation in this area.

We appreciate that CMS solicited comments in 2022 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 as an alternative to the criterion based on FDA label to allow the recommendations of specialty societies or other national organizations such as medical compendia developers.* 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 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 and pays for drugs that are administered at the time of ophthalmic surgery, and have an FDA-approved indication to treat/prevent post-operative issues, such as pain and other sequelae of ophthalmic surgery, including inflammation, and in the future, infection, separately under Medicare Part B.**

With respect to other related and relevant implementation issues:

- We strongly supported the agency’s 2022 proposal to provide continued payment for drugs and biologicals with expiring pass-through status. We recommend that CMS exercise its equitable adjustment authority and extend pass-through status for any drug on pass-through during the full extension of the Covid-19 public health emergency.
- We urge CMS to adopt refinements to the non-opioid authorities to help ensure patient access to drugs, like Dexycu, that were marketed prior to 2022 but that now must seek an FDA label expansion for pain indications before they can be eligible for such status. This can be accomplished by temporarily “grandfathering” for two or three years these products so that payment doesn’t lapse pending eligibility for non-opioid status.
- We likewise support the extension of separate payment for qualifying products in the hospital outpatient setting. Recent data demonstrate that the lack of separate payment for these drugs in the HOPD setting following the expiration of its pass-through status resulted in a significant drop in utilization of products in the HOPD. This was in contrast to the stable utilization in the ASC setting where Omidria continued to be paid separately as a non-opioid pain management drug. In response to CMS’ request for comments on expanding the policy to the HOPD setting, our organizations support the expansion because it would harmonize beneficiary access to non-opioid pain management products across settings of care.
- We recommend that CMS continue to use the standard ASP + 6% payment methodology to mitigate payment differentials across settings.

STANDALONE MIGS SERVICES

Under current authorities, when a micro-invasive glaucoma surgery (MIGS) is performed without a cataract procedure, the surgeon utilizes CPT code 0671T ((Insertion of anterior segment

aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more). When the service is furnished in an ASC, Medicare pays the ASC facility fee for CPT code 0671T based on the assignment of the code to Ambulatory Payment Classification (APC) 5491, with a current payment rate of \$1,600.70. For CY 2023, CMS would continue to assign the procedure to APC 5491 and the proposed ASC rate is \$1,639.89. We have been and remain deeply concerned that payment for CPT code 0671T will dramatically undercompensate facilities for this service.

To address the issue, **CMS should ensure access to standalone MIGS procedures by reassigning CPT code 0671T to APC 5492.** We do not understand the basis for this proposal since this code is for a standalone MIGS procedure just like now retired CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion) was, and that code was always assigned to APC 5492. In fact, the language of the CPT codes 0671T and 0191T is virtually identical. For 2022, CMS assigned CPT code 0671T to APC 5491 based on its view that the procedure, clinically, is more similar in scope to procedures assigned to APC 5491.

We strongly disagree with this determination. Indeed, CPT code 0671T is more similar clinically to procedures that are assigned to APC 5492, such as CPT code 0449T (Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device) and CPT code 0253T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space). These two procedures, and the one reported with CPT code 0671T, are for the insertion of an aqueous drainage device in the eye. As a result, APC 5492 is a better clinical match for CPT code 0671T than APC 5491. We also understand that there are 2021 claims data for standalone MIGS procedures that show a geometric mean cost that is much higher than the geometric mean cost for APC 5491 and is even higher than the geometric mean cost for APC 5492. Thus, considering resources expended for the procedure, as measured by the 2021 claims geometric mean, APC 5492 is the proper APC for CPT code 0671T, which is in-line with the recommendation of the HOP Panel, which stated “that CMS assign HCPCS code 0671T, *Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more*, to APC 5492, *Level 2 Intraocular Procedures.*”

Our organizations believe that the proposed payment for standalone MIGS procedures is too low and embodies the potential to impede the glaucoma patient’s access to these vital services in the ASC. **AAO, ASCRS, ASRS, OOSS, and SEE strongly recommend that the agency assign CPT code 0671T to APC 5492 given the available data and clinical similarity of the procedure to other procedures in that APC and in accordance with the HOP Panel recommendation.**

PAYMENT FOR DEXTENZA

DEXTENZA (Dextenza) is approved for the treatment of ocular inflammation and pain following ophthalmic surgery and is reported using J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg). Dextenza is a physician-administered corticosteroid intracanalicular insert that is inserted following an ocular procedure and is currently reported using Category I Current Procedural Terminology (CPT®) code 68841 (Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each).

CMS's proposal to assign CPT code 68841 to APC 5694 with a proposed payment rate of \$338.58 in the hospital outpatient setting with no separate reimbursement in the ASC setting due to the APC's OPSS status indicator of Q1 is arbitrary and irrational and should not be finalized since the level of payment is inadequate for hospitals and results in no payment to an ASC for the procedure. Importantly, the treatment of this procedure is also entirely inconsistent with how CMS proposes to pay for other similar ocular medication delivery procedures involving similar drugs to Dextenza, such as Dexycu.

Failure to provide payment for the procedure when other similar procedures would be paid separately, e.g., CPT 0699T & 66030, creates a disincentive for this product to be utilized in the ASC. This insertion procedure is a distinctly separate procedure that requires additional time and resources following completion of the primary ophthalmic surgical service. Despite the similarity of the procedures noted above, CMS proposes to assign codes 66030 and 0699T to APC 5491 with a proposed payment rate of \$2,201.12, while paying for CPT 68841 at \$338.58. Furthermore, adequate single frequency claims data for 68841 is now available with a geometric mean cost of \$2,227.06. Additionally, the HOP Classification Panel has recently recommended to CMS that 68841 be reassigned to APC 5503 (payment rate \$2,043.70) based on the available single frequency claims data. Based on the relative resource parity of 68841 to 66030 and 0669T, the available single frequency claims data, and the HOP Panel recommendation, **CPT code 68841 should be assigned to APC 5503 with a J1 status indicator.**

DEVICE INTENSIVE PROCEDURES

Our organizations are appreciative of the agency's efforts to address the device-intensive threshold and its impact on ASC volume. The agency's recognition of the important role that devices play in our ability to perform surgical procedures – by reducing the devices threshold over the past several years from 50 percent to 40 percent and then to 30 percent and by establishing that the threshold determinations should be based on the percentage the device accounts for in the surgery center as opposed to the percentage in the HOPD -- has enabled our members to offer more high-quality services to our patients at great savings to the Medicare program and its beneficiaries.

Recent changes to the device-intensive threshold have greatly increased the number of device-intensive codes on the ASC-CPL, but it has also shone a spotlight on how the lack of complete alignment in the HOPD and ASC payment systems serves as a barrier to access for Medicare beneficiaries. While there is a statutory cap on the patient responsibility when a procedure is done in a hospital, including an HOPD, that policy is not in place for the ASC setting. Even though the Medicare beneficiary's patient responsibility is capped, the hospital is made whole by the Medicare program. Beneficiaries who would otherwise have access to the high-quality, convenient ASC setting are disadvantaged by this lack of alignment in policy. **We recommend that CMS join the ASC community in encouraging Congress to implement an ASC copayment cap with respect to devices implanted during surgery in an ASC.**

Because of the copayment cap and its impact on many device-intensive codes, there are many areas, particularly in rural communities, where the wage index is so low that it makes it financially unsustainable for rural facilities to provide certain device-intensive procedures to Medicare beneficiaries. **To address this concern, CMS should refrain from adjusting the**

device portion of the payment by the local wage index. This is consistent with the Agency’s policy for separately payable drugs and biologics, and it is highly unlikely that a facility in a rural community is getting a better deal on devices than ASCs in large cities.

We are concerned with the agency’s device-intensive offset calculation for *insertable devices*. Devices that are insertable, *i.e.*, not retained in the body post-procedure, as opposed to *devices that are implantable*, were not being reported accurately by HOPDs throughout 2021 and are, therefore, not included in the cost calculation for device-intensive designation. The under-reporting of insertable device costs results in the denial of such status for procedures using insertable devices. Effective January 1, 2019, CMS modified the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether they remain in the body following the procedure, to qualify as device-intensive procedures; this status was previously reserved for procedures with implanted devices.

There is no clear revenue code for HOPDs to use to report costs for insertable devices. Revenue Code 278, which applies to “Other Implants,” has historically been used for devices that remain in the body with no reference to insertable devices. Yet, CMS’ methodology for calculating the device offset percentage relies upon accurate reporting of device costs to Revenue Code 278. We appreciate that CMS issued additional guidance in March 2022 regarding the process for HOPDs to report insertable device costs. Unfortunately, due to the delay in hospital cost reporting and the determination of device intensive status based on historical claims data, this guidance does not address the past cost-reporting errors that have under reported device costs and have skewed CMS’ device-intensive determination for procedures such as CPT 66174 (canaloplasty).

Using the example of glaucoma procedures such as canaloplasty (CPT 66174) which require an insertable device, it is evident that CMS’ claims data do not accurately account for the cost of the eligible insertable device when calculating the percentage of device costs because these device costs are not reported by HOPDs under the CMS methodology. As we noted last year, analysis of 2019 Medicare claims revealed that, instead of reporting device costs under an eligible device HCPCS code and/or Revenue Code 278, most hospitals did not capture the device costs for CPT 66174 in a way that factored into CMS’ device offset calculation, hence, leaving the device’s true costs unreported. In fact, only approximately 20 percent of claims submitted with CPT 66174 reported any device cost using the appropriate revenue code to be used in the device intensive calculation. Analysis of 2021 claims data reflects that there is still a high degree of confusion regarding how hospitals should report costs for these insertable devices. *Use of flawed data has resulted in CMS denying device-intensive status for canaloplasty, while other procedures, such as MIGS implants and aqueous shunts, which are implantable, have costs reported accurately because an existing Revenue Code exists (0278) to describe such devices.*

When faced with clearly inconsistent or inaccurate cost data reporting, the agency has historically adjusted the calculation methodology to avoid an inequitable payment policy. **We strongly recommend that the agency use an alternative data set, such as a subset of accurate hospital claims data or manufacturers’ invoices, to calculate the device-offset percentage, thereby safeguarding patient access to procedures that would otherwise be cost-prohibitive in the ASC setting. On an interim basis, we request that CMS exercise its discretionary authority as it has done in the past and address the remaining short-term gap in cost reporting by establishing, effective January 1, 2023, a temporary adjustment for CPT 66174 that reflects accurate data on devices costs.** We believe this temporary policy will recognize

the clinical needs of glaucoma patients along with CMS' policy requirements for CY 2023, while also allowing hospitals to follow CMS' March 2022 guidance to report correct device costs for CPT 66174 in the CY 2024 rulemaking cycle.

NEW TECHNOLOGY IOL (NTIOL) PAYMENT RATE

Embedded in our comments is the premise that 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 in a cataract surgery. Since 1999, when CMS established the payment rate for a new NTIOL at \$50 per lens, there has not been a payment adjustment. While there have been major technological advances in IOLs over the last two decades, there continues to be addressable unmet needs for post-cataract patients, including enhancing lens quality, reducing secondary interventions, and addressing negative dysphotopsia. In the final rule, our organizations request that the agency update the NTIOL payment rate of \$50 to \$86.49, 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 behind 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 several new monofocal IOL technologies. These future IOLS have the potential to provide meaningful outcomes for cataract patients. One such innovation is the open capsule bag IOL design. This innovative IOL is designed to limit the IOL material from interacting with the capsule bag. The lack of interaction mitigates the migration of epithelial cells from the capsule bag which creates an opaque layer at the back of the capsule. This opaque layer is difficult to see through, resulting in blurry vision for the patient. Additionally, the opaque layer (medically known as a posterior capsular opacity) is the top major cause for a second 'cataract' procedure, the yttrium-aluminum-garnet ("YAG") laser capsulotomy. This second procedure exposes patients to the potential risk of procedure complications and increases CMS healthcare costs as the YAG laser capsulotomy is a commonly needed procedure (in 2019 was the sixth highest volume procedure performed in ASCs).

Another innovative technology improves intermediate vision provided by a higher-order aspheric monofocal IOL optic design. The IOL is designed to deliver functional vision benefits that improve patient mobility and confidence. Indeed, the improved functional intermediate vision benefits reported extend beyond vision impacting patient's quality of life.

A third example of important innovation reported to be in development is a drug eluting monofocal IOL designed to prevent many cataract surgery complications, such as inflammation and infection. Post-cataract, patients are prescribed a multi-drop regimen that can be costly and

complicated for patients to self-administer. Although risk mitigation is the target, an increased patient satisfaction may be realized as the number and frequency of eye drops needed after cataract surgery would be reduced. This reduction in post-operative eye drops may also reduce health care prescription drug expenditures under Part D for cataract patients.

In order to meet CMS’ original objectives to enable Medicare beneficiaries’ expedited access to new technologies, we strongly encourage CMS to consider increasing the per lens payment from \$50 to \$86.49 in CY 2023. 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.

PAYMENT FOR ARTIFICIAL IRIS CODES

AAO, ASCRS, ASRS, OOSS, and SEE urge CMS to assign the three artificial iris implantation codes (0616T, 0617T, and 0618T) to APC 5495 Level 5 Intraocular Procedures.

With their pass-through status expiring at the end of 2022, CMS should reassign these three codes to higher-paying APCs for 2023 to account for the cost of the packaged artificial iris. CMS has proposed that 0617T and 0618T be assigned to APC 5495. We agree with these proposed assignments and urge CMS to finalize them. However, we disagree with the assignment of CPT code 0616T to APC 5493 (Level 3 Intraocular Procedures) and recommend that CMS assign CPT code 0616T to APC 5495 in the 2023 OPSS/ASC final rule.

Our understanding is that the majority of the cost associated with providing each of these services (0616T, 0617T, and 0618T) is the cost of the artificial iris. Compared with the cost of the device, the cataract with IOL portion of 0617T and the secondary IOL portion of 0618T each contribute little to the total cost of 0617T and 0618T, respectively.

CMS’s claims data demonstrate that the APC 5493 payment rate is grossly insufficient considering the costs associated with CPT code 0616T. The payment rate for APC 5493 in both the OPSS and ASC is only \$7,434, while the geometric mean cost of the 0616T claims is \$12,847. The geometric mean cost of 0616T is very close to the geometric mean cost of 0618T (\$12,847 for 0616T versus \$13,257 for 0618T). However, if CMS finalizes the assignment of CPT code 0616T to APC 5493 then the artificial iris (without concomitant cataract surgery with IOL or secondary IOL implantation) will not be available to Medicare beneficiaries because the payment rate is significantly below the device cost and only a fraction of the total cost of 0616T. Therefore, we urge CMS to assign 0616T to APC 5495 in the 2023 OPSS/ASC final rule.

UNLISTED CODES

An important anomaly in CMS’ effort to align the ASC and HOPD payment systems 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 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 clear safety rationale for this policy and 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 very much appreciate the efforts undertaken by CMS to implement the ASC Quality Reporting Program over the past several 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 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, we have strenuously objected to the application to ASCs of Measure ASC-11 (NQF 1536): *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 purposes of mandatory reporting by facilities and were disappointed that this measure, misguided in its application to the ASC, was included in the final 2022 rule. **While we support the agency's recent decision to defer implementation of ASC-11 until after the Covid-19 public health emergency, our organizations strongly believe that ASC-11 should be withdrawn altogether.**

NQF 1536, from which it 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

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.

- **The data required for reporting by facilities should be available within the records of the ambulatory surgical center; facilities should not be required to access and report data that is only available to other providers, such as the physician’s office.**

Even if NQF 1536 was to be tested and resubmitted for endorsement by NQF at the facility level, there are insurmountable barriers to collecting data for these measures within the ASC. *All the currently implemented ASC quality measures utilize data that is housed within and collected by the ASC itself. This new measure requires reporting on data that is located in the surgeon’s office and is wholly inaccessible by the ASC.*

Data collection for ASC measures is complicated by the fact that ASCs are administratively and financially separate from physician offices. Under the Medicare program, an ASC operates exclusively for the purpose of furnishing ambulatory surgical services to patients requiring such a setting. Although the governing regulations permit the surgical facility to exist adjacent to a physician’s office under certain circumstances, Medicare ASC Conditions for Coverage state very clearly that the two entities must be physically, administratively, and financially separate from one another. *Importantly, medical record keeping must always be maintained separately and exclusively from other operations.* While CMS has referred to NQF 1536 as a “chart-based” measure, none of the data necessary to appropriately comply with the measures are located in the ASC patient records. In other words, even though a physician in the clinic may perform surgery in the ASC next door, the medical records of one entity are *never* readily accessible by the other. As a practical matter, the ASC is staffed by registered nurses, operating room technicians, and clerical staff who are neither qualified to evaluate surgical outcomes nor located in the physician’s office where pre-operative and post-operative care might be efficiently and accurately evaluated.

- **It is not appropriate to migrate a measure across settings of care that was not considered in the design, testing, and implementation of the measure and with respect to which the measure is not actionable by the facility.**

ASC-11 is inappropriate for reporting (mandatory or voluntary) by the ASC because facilities are not equipped to evaluate potential cataract outcomes. The facility is not involved in the baseline events preceding the surgery against which outcomes are measured in the post-surgical events that encompass the healing process. It is inconceivable that the ASC, which is neither licensed nor qualified to evaluate the cataract patient and make these assessments, would be involved in the professional decision-making contemplated by the measure. *Any improvement in visual function would be attributable to the individual surgeon, not to the facility where the surgery occurred.* Physician-level measures such as those incorporated within the Quality Payment Program (OPP) are formulated to assess quality *within the physician’s office.*

Importantly, *NQF 1536 has not been tested nor endorsed as a facility-level measure for the ASC setting.* Indeed, the Measures Application Partnership (MAP), in reviewing the measure, admonished that it should be tested and NQF-endorsed for the facility level of analysis; this has not occurred.

The goal of the ASC QRP should be to reflect those aspects of patient care that are within the control of the facility (e.g., patient safety, staffing, equipment) and for which it is reasonable to hold the ASC accountable. The surgeon's decision to recommend cataract surgery is based upon factors other than the potential for functional benefit – visual acuity and visual impairment are also considered. *It is inconceivable that the ASC, which is neither licensed nor qualified to evaluate the cataract patient and make these assessments would be involved in the professional decision-making contemplated by the measure.* As discussed above, a measure should be applied to the ASC only where actions that might be undertaken to improve such quality are within the purview of the facility. *We do not believe that it is possible for ASCs to influence outcomes with respect to this measure; therefore, it is not appropriate to include the measure in the ASC Quality Reporting Program.*

- **Implementation of this measure in the facility would be extremely burdensome and resource-intensive for the reporting ASC.**

The burden on ASCs to disseminate, collect, and report on this measure would be significant – even in a survey with a modest number of patient respondents-- given that the facility's exposure to the patient is essentially limited to the care provided at the ASC on the day of surgery. The measure requires that patients complete a visual function questionnaire both before and after their scheduled surgery. The results of the pre- and post-surgery questionnaires are then compared to assess patient-perceived improvement. The patient's visual acuity is measured before and after surgery in the physician's office, not the ASC. Single-specialty facilities like ophthalmic ASCs tend to be smaller, have fewer operating rooms and employees, and, typically, will have available diminished resources to meet the administrative burdens posed by regulatory initiatives like quality reporting.

These burdens are not trivial. The measure contemplates the administration of two visual function patient questionnaires, one completed by the patient prior to surgery and the other completed during the 90-day period following surgery. These survey instruments would be delivered to the patient during his pre-op and post-op visits *with the physician*. Facilities would be required to contract with an outside entity to administer pre- and post-surgical surveys and tabulate the results, a burdensome and expensive exercise considering the number of cataract surgeries performed in surgery centers, or somehow mandate that surgeons on the medical staff of the ASC conduct visual function surveys as a condition of maintaining ASC staff privileges. The process contemplated with respect to reporting on the measure, whether performed on a mandatory or voluntary basis, places the ASC in the arbitrary and unworkable role as “middleman” between the physician and the government. The numerous modifications to the manual specifications for ASC-11 -- which have continued to be confusing, ambiguous, and unrealistic – reflect the monumental challenge that even the agency has encountered in clarifying just what would be expected of facilities.

- **Adoption of ASC-11 would not produce data that is actionable by the ASC, and, as such, does not embody the potential to improve the quality of care provided by the ASC.**

Finally, the surgeon's decision to recommend cataract surgery is based upon factors other than the potential for functional benefit – visual acuity and visual impairment are also considered.

It is inconceivable that the ASC, which is neither licensed nor qualified to evaluate the cataract patient and make these assessments, would be involved in the professional decision-making contemplated by the measure. As discussed above, a measure should be applied only where actions that might be undertaken to improve such quality are within the purview of the facility. *We do not believe that it is possible for ASCs to influence outcomes with respect to this measure; therefore, it is not appropriate to include the measure in the ASC Quality Reporting Program.*

We strongly recommend that ASC-11 be permanently withdrawn as an ASC quality measure.

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 TASS (Toxic Anterior Segment Syndrome) within two days of undergoing anterior segment surgery in the ASC. The measure was reviewed by the Measures Applications Partnership (MAP) four 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. The incidence of TASS is measurable, attributable to the ASC, and is actionable by the facility. 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 underreported 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.**

Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2023 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@ao.org, 202.737.6662; Jillian Winans, Senior Manager of Government Relations, ASCRS, jwinans@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.

Thank you for 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**