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The Honorable Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850
Submitted via: regulations.gov

Re: [CMS-1770-P] Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies; and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure,

The American Academy of Ophthalmology (the Academy) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the CY 2023 Medicare Physician Fee Schedule (MPFS) and the CY 2023 Quality Payment Program (QPP). The American Academy of Ophthalmology 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.

Provided below is an executive summary of key points, comments, and concerns of the Academy regarding the policies within the CY 2023 MPFS proposed rule. These comments are fully developed in the body of this letter along with additional issues and comments not highlighted in the summary.

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Executive Summary

The Academy disagrees with several proposals in the MPFS that distort relativity in the resource-based relative value scale (RBRVS) and promote inequity among physicians under Medicare. We are deeply alarmed by the growing financial instability of the Medicare physician payment system.

There is an urgent need for policy intervention to address the drastic cut to the 2023 proposed MPFS conversion factor (CF). The Academy has outlined below numerous harmful impacts to physicians, and consequentially patient care access, driven by the conversion factor's failure to appropriately keep up with growth in other areas of healthcare spending and overall inflation.

If Congress does not act to preserve physician reimbursement by the end of 2022, budget neutrality cuts, as well as the delayed 3% E/M cuts, will cause serious disruption to physician practices in 2023.

We are advocating that before the end of the year, Congress:

- Extend the congressionally-enacted 3% temporary MPFS increase in the conversion factor;
- Provide relief for the additional 1.5% budget neutrality cut that is planned for 2023;
- End the statutory annual freeze and provide an inflation-based update for the coming year; and
- Waive the 4% PAYGO sequester necessitated by passage of legislation unrelated to Medicare

As a result, the Academy is aligned with the American Medical Association (AMA) in asking that Congress provide a positive update to the Medicare conversion factor in 2023 and all future years. **We urge CMS to engage with Congress as they work to ensure appropriate physician reimbursement, reform the Medicare payment system and provide continued stability for physicians.** At a minimum, CMS should exercise its authority to do what it can to reduce the negative impact of policy changes on physicians providing care for Medicare beneficiaries.

While we are encouraged that CMS has requested stakeholder feedback on the valuation of global surgical packages, we are disappointed that CMS has not applied payment equity to post-operative visits included in the global surgical payment, even after previous substantial recommendations from the surgical community. Ever since CMS announced the changes to evaluation and management (E/M) services

in 2019, the Academy and many other surgical societies have objected to this decision not to apply it universally as they have previously. **We believe CMS must apply the E/M payment increases to the post-operative visits in the global codes and provide equitable treatment to surgical specialties while they continue to review recommendations/data.**

We are disappointed that CMS is proposing to accept only 75% of the total Relative-value Update Committee (RUC) recommendations for CY 2023. We urge CMS to continue working with the RUC as it is the most representative consensus of all medical specialties regarding physician work and expenses. While we are pleased to see that CMS has taken the expertise of the RUC into account for many of our Ophthalmic codes, **we do urge CMS to consider the clarification and clinical expertise the Academy is providing in our detailed responses to proposals CMS has put forward on several ophthalmic procedures.**

Several ophthalmic surgical codes have been nominated by a third-party as potentially misvalued due to lack of valuation in the office setting. To address CMS's request for feedback, the Academy randomly surveyed our membership and found **the absence of published patient safety data, outcomes data and office certification standards are primary concerns.**

The Academy urges CMS to revisit its approach to full measure testing for QCDR measures as they delay this requirement for an additional year. We also recommend that CMS discontinue automatic application of the Extreme and Uncontrollable Circumstances (EUC) Hardship for MIPS reporting year 2022. Eligible clinicians who are affected by the pandemic or other circumstances should be able to apply for a hardship exemption on a case-by-case basis. Finally, the Academy believes that instead of overly complicated programs, physicians who actively participate with benchmarking in a CMS approved EHR-based QCDR should be recognized as being fully compliant with Merit-based Incentive Payment System (MIPS).

We also want to highlight our significant concerns over the addition of Optometry to the Ophthalmology specialty set for MIPS measures. These two types of practices have major differences in patient populations and abilities to perform eye surgery procedures that this combination would not sufficiently acknowledge. Haphazardly merging two distinct specialties like this is not a step that should be taken lightly. The Academy believes this kind of action could pose significant risks to patients.

We appreciate the consideration of our detailed QPP comments and opportunity to work closely with CMS to ensure our members' practices can succeed in the MIPS or other payment tracks such as MIPS Value Pathways (MVPs) or Alternative Payment Models (APMs). Please find our detailed comments for both the CY 2023 MPFS and QPP in the subsequent sections.

Specific Issues in the Medicare Physician Fee Schedule

CY 2023 NPRM Conversion Factor

For CY 2023, the proposed conversion factor is $33.08, a decrease of $1.53 from the CY 2022 conversion factor of $34.61. For more than 20 years, Medicare physician reimbursement has been under substantial downward pressure due to flaws in the payment system's design. Medicare physician payments have remained constrained by a budget-neutral financing system that lacks an automatic inflation-related update mechanism similar to those in place for other Medicare providers such as hospitals and skilled nursing facilities. When adjusted for inflation, Medicare physician pay experienced a decline of 20% from 2011 to 2021.[1]

The Academy is aligned with the AMA in asking that Congress provide a positive update to the Medicare conversion factor in 2023 and all future years. **We urge CMS to engage with Congress as they work to ensure appropriate physician reimbursement, improve the Medicare payment system and provide continued stability for physicians.** At a minimum, CMS should exercise its authority to do what it can to reduce the negative impact of policy changes on physicians providing care for Medicare beneficiaries.

Determination of PE RVUs

Strategies for Updates to PE Expense Data Collection and Methodology

While the Academy is open to ideas of future reforms to the methodology informing indirect Practice Expense data in furtherance of the consistency, transparency, and predictability of these inputs, we strongly support continued use and refinement of the AMA-conducted Physician Practice Information Survey (PPIS) to source data inputs for indirect Practice Expense value. We have more confidence in this approach than in alternative methodologies or data sources that may be identified or modeled by outside consultants and/or non-clinicians who lack specific and direct experience in their respective specialties. Direct input from physician and select nonphysician practitioners, made possible by the PPIS process, is integral to the stated objectives of

[1] American Medical Association. (2022, July 26). *Medicare updates compared to inflation (2001-2021).* https://www.ama-assn.org/system/files/ama-medicare-gaps-chart-grassroots-insert.pdf

transparency and predictability, along with fairness when moving to update indirect PE allocations.

Separately, CMS acknowledges that interested parties have objected to certain costs they believe are not associated with increased indirect PE being incorporated into existing PE allocation methodology. The Academy asks that if CMS does re-evaluate which costs contribute to indirect PE values in the future, any potential changes to what gets included in indirect PE costs should be subject to the full rulemaking process, with public comment and analysis modeling specialty impacts.

CMS also expresses a need to establish a roadmap towards more routine PE updates in future rulemaking. The Academy supports this suggestion, as well as the need to update out-of-date PPIS data, which was last collected in 2007-2008. Approaching updates on an irregular, or greater than 10-year basis surely exacerbates the concerns regarding "increasingly out-of-date data sources" and a failure to reflect "evolving business models" in health care that CMS acknowledges.

However, we note a need for pricing stability as CMS implements updates, particularly for rural, independent, and/or smaller medical practices. We support the CMS suggestion that any future roadmap to regularly scheduled PE updates does include consideration of the burdens data collection and re-education of billing staff can place on clinicians; and support the use of staggered implementation, particularly for abnormally large value adjustments.

Global Payments

While we appreciate CMS seeking our input on global surgical package valuation in the proposed rule, we note the Academy and our surgical community partners have provided thoughtful feedback and reasonable solutions for nearly a decade. That public feedback has been largely ignored, and lack of equitable adjustments are negatively impacting the relativity and the validity of the fee schedule. We are frustrated that CMS has refused to appropriately adjust the 10- and 90-day global surgery codes to apply recent increases in valuation of the office evaluation and management (E/M) codes to postoperative visits included in the global package. Postoperative visits have experienced identical increases in physician work and practice expense to those of office E/M services for the same reasons the latter were updated. Relative Value Update Committee validation and CMS codification of code levels has been ongoing for years, ensuring that the correct E/M

crosswalks and number of postoperative visits are regularly updated to reflect current practice patterns.

Ophthalmology services are a prime example of why CMS' current policy to withhold payment equity for postoperative office visits in the global period is flawed. The Medicare statute specifically prohibits CMS from paying different physicians differently for the same work, and the "Secretary may not vary the . . . number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician".[2] Failing to adjust the global codes is equivalent to paying some physicians less for providing the same exact level of E/M services.

It also disrupts the relativity of the fee schedule. Without an adjustment to the global codes, the bedrock of relativity within the fee schedule is degraded, and future work by the RUC and CMS will progressively deviate from the established relative value of different physician services across the fee schedule in ways that are certain to compound imbalances to the RBRVS.

The failure to apply updated E/M valuations to global surgical packages exacerbates health disparities. The policies CMS implements, or chooses to not implement, have broad implications on how commercial payors and Medicaid reimburse physicians. With many states basing their Medicaid reimbursement on Medicare values, 2022 payment reductions for strabismus surgery have affected access for vulnerable children, further exacerbating existing disparities in the diagnosis and treatment of pediatric strabismus. Untreated strabismus can lead to permanent loss of vision in one eye and loss of depth perception, limiting vocational opportunities for those affected. If CMS improves the Medicare payment of these global codes through equity adjustments to the built-in E&M post-operative visits, it will help mitigate payment reductions for Medicaid services that disproportionately affect vulnerable populations or the providers who serve them.

The Academy, in alignment with the AMA and surgical specialties, strongly believes CMS must apply the increased 2021 valuation of the office E/M visits to the postoperative visits incorporated in the surgical global packages. The House of Medicine, through the RUC has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values in the global codes. CMS, however,

[2] U.S. Congress. (1934) United States Code: Social Security Act, Sec. 1848. [42 U.S.C. 1395w–4] (a). https://www.ssa.gov/OP_Home/ssact/title18/1848.htm

did not take this action and instead rejected the recommendation causing serious inequities since the 2021 physician fee schedule.

Nevertheless, we remain committed to working with the Agency to ensure global surgical codes are valued appropriately and we offer the following comments in response to CMS's request for information for data and strategies to improve global surgical package valuation.

Data Collection, Analysis, and Findings

CMS has raised the concern that the current valuation of global surgical code E/M services provided during the post-operative period is not equal to stand alone E&M office visits and seeks comment on other sources of data that would help assess global package valuation. The agency continues to give credence to the three, now updated, reports done by the RAND Corporation on global surgical code valuation, though those reports were heavily criticized for inadequate sample size, poor response rates, and computational errors.

We believe an extensive process already exists to determine the appropriate value for global services through the Relative Value Update Committee (RUC). CMS may accept, modify, or reject the RUC recommendations through the rulemaking process; thereby, giving the agency the ultimate determination of whether the E/M services reflected in the global package are accurate. **If CMS feels that specific global codes are "misvalued," the agency should look to the AMA's RUC review process to update codes in order to ensure global payments accurately reflect the actual services and postoperative visits being provided to patients.** This process is supported by all specialties.

When RUC survey respondents provide their input on physician work required to perform a service, the postoperative visits are part of the RVU valuation recommendation. Instead of relying on extrapolated data, responses from RUC surveys come directly from the physicians most familiar with the patients and services being provided.

Changes to Healthcare Delivery and Payment for E/M Services

It should be noted that the RAND reports were completed prior to the recent revisions to office/outpatient-based E/M level of medical decision-making selection, which CMS adopted as finalized policy

effective January 1, 2021. In acknowledgement of the recent changes in the coding and valuation of separately billable E/M services, CMS is asking for comments on the impact to global surgical packages.

Based on our experience with the RUC process, it is clear that the medical decision making during post-operative visits included in the global package for ophthalmic surgical services is identical to if not greater than that associated with the corresponding, separately billable E/M services. Comorbidities do not disappear during the post-operative global period. In contrast, it is not unusual for surgery to destabilize comorbid conditions such as diabetes, hypertension, or glaucoma, that were stable prior to surgery. Ophthalmologists, therefore, must also consider the complexity of problems and complications and/or morbidity or mortality of patient management just as they would do for a separately billable E/M visit.

To demonstrate the medical decision making involved in post-operative office visits, we illustrate with Current Procedural Terminology (CPT) 66984, *Extracapsular cataract removal with insertion of intraocular lens prosthesis without endoscopic cyclophotocoagulation*, as an example below. **Examples of equivalency for post operative visits in other ophthalmic procedures can be found in Appendix A.**

In accordance with 2021 updates to office/outpatient E/M coding, typical post-operative billing for CPT 66984, *Extracapsular cataract removal with insertion of intraocular lens prosthesis without endoscopic cyclophotocoagulation* based on a typical patient is as follows:

1. Number and/or Complexity of Problems Addressed at the Encounter: Low: 1 stable chronic, or 1 acute uncomplicated = 99213
    a. Depending on how one defines the follow up for cataract surgery, the visits may be listed as either 1 acute uncomplicated problem (recent cataract surgery that was successful with a diagnosis of nuclear sclerosis, cortical cataract, or posterior subcapsular cataract), or 1 stable chronic condition (nuclear sclerosis, cortical cataract, or posterior subcapsular cataract). Neither problem is "self-limited" as without proper management, neither will resolve on its own without intervention. Not operating will lead to progressive vision loss (cataract is the leading cause of blindness in the world), and patient non-compliance during the postoperative period can lead to serious vision loss from uveitis, macular edema, or posterior synechiae threatening pupillary block, iris bombé, and acute glaucoma.

2. Amount or/or Complexity of Data to be Reviewed and Analyzed: Minimal or none = 99212
    a. Tests such as OCT of the macula may be performed if medically necessary, but these are separately billable and thus not counted.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management: Moderate = 99213
    a. Prescription drug management is performed at every visit in the post-op period, including but not limited to changing the dosages of steroids and adding or adjusting medications in the immediate post-operative or later post-operative periods to adjust for intraocular pressure elevations (due to retained viscoelastic at the first visit or steroid-related ocular hypertension at later visits as needed), intraocular inflammation, corneal edema, epithelial defects, post-operative keratitis, dry eye, and other issues.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded; thus, CPT 99213 would be justified based on current E/M billing rules.

It is important to note that CPT 66984 went through revaluation during the 2019 rulemaking cycle and CMS agreed with the RUC's recommendation that the global surgical payment period includes three postoperative visits for CPT 66984 (one 99212 and two 99213 visits). As shown above, based on the updated medical decision-making coding rules, for the typical patient, ophthalmologists are performing three level 3 visits within the global surgical period and should be receiving higher E/M reimbursement for CPT 66984 than recommended by the RUC in 2019 and accepted by CMS. Given CMS' recent acceptance of the RUC recommendations, there is no reason why ophthalmologists should be paid less for E/M visits than other physicians who are providing the same level of service per visit. Failing to adjust the global codes results in paying some physicians less for providing the same exact level of E/M services.

CMS has been at the table for valuation of surgical packages like this for over 120 procedures since Congress directed them, after passage of MACRA, to suggest alternative approaches for accurate valuation.

Strategies to Address Global Package Valuation

CMS presents several possible scenarios for a global service revaluation process, including strategies that would evaluate all 10- and 90-day

global packages at one time, revalue only the 10-day global packages, or revalue all the 10-day global packages and some 90-day global packages. We urge CMS to avoid bringing all 10- and 90-day global packages up for evaluation at one time. Such a drastic change would create severe instability in the physician reimbursement system, which has already been stressed by the COVID-19 pandemic. A multi-year process, evaluating some 10-day global packages and some 90-day global packages in each year, would ease the shock to the payment system and also allow stakeholders and CMS the benefit of learning from each iteration.

We believe CMS should focus on the 10-day global packages first. While we do not agree with RAND, the data do suggest that there may be a greater probability that post-operative E/M visits for some of these codes may not be consistently provided.
Again, we recommend utilizing the well-established and widely accepted Relative Value Update Committee (RUC) misvalued codes process, which allows input from all stakeholders involved in the valuation process, including CMS. When choosing which codes to nominate, CMS should also consider the impact to the specialties using the codes. Focusing on all codes for just one or two specialties in each round of evaluation would put undue burden on the specialty societies that coordinate the RUC surveys. A better approach would be selecting global packages from multiple specialties.

Before considering revaluation of global surgical packages, CMS must increase the E/M portion of the global codes. To do otherwise creates differentials in how specialties are paid for the same work, disrupts the relativity of the fee schedule, and has significant impacts on how commercial payors and Medicaid reimburse physicians.

We strongly urge CMS to apply the CMS approved E/M payment changes to the E/M values that are a component of the global codes in the final CY 2023 Medicare Physician Fee Schedule.

Nominations of Potentially Misvalued Services Under the PFS

As the result of an interested party's nomination, CMS requests comment on the relative merits of existing facility values versus the potential for developing non-facility values for numerous ophthalmology service codes for cataract, glaucoma (MIGS), and vitrectomy procedures (CPTs 65820, 66174, 66982, 66984, 66989, 66991, 67015, 67036, 67039, 67040, 67041, 67042, 67043, 67108, 67113). These codes are not

misvalued, but rather, are not valued by CMS. This proposal would represent the most significant expansion of ophthalmic office-based surgery in recent history and create impacts specialty-wide. As a result of this significance and the Academy's responsibility to advocate for the interests of our patients and their physicians, we will directly address the nominator's rationale as relayed both to and by CMS in its 2023 MPFS proposed rule.

Survey of Ophthalmologists on Office-Based Surgery

The Academy has reviewed the nomination materials submitted by a representative of iOR Partners, the "only company dedicated to (launching) office-based surgery suites" in partnership with interested ophthalmic physician practices.[3]

While we appreciate the nominator's idea to expand and improve delivery of these ophthalmic procedures, these views do not appear to represent the current views of most ophthalmologists nationally. In response to publication of the 2023 MPFS Proposed Rule, the Academy conducted a web-based survey in August 2022 to assess our members' receptiveness to expanded office-based delivery & Medicare reimbursement for six of the most commonly performed nominated procedures. We randomly sampled 2,500 practicing ophthalmologists who, based on their self-identified subspecialty area, likely perform at least one of the nominated procedure codes. This survey was open from 8/2/2022 to 9/1/2022 and received a statistically significant number of anonymous responses (n=317).

For each of the respective procedure-categories surveyed, the overwhelming majority of physician-respondents (with a relevant clinical focus and who currently perform these procedures) currently choose not to offer those services in an office setting.

- Cataract/IOL: (CPT 66982, 66984): 90.3%
- Cataract/IOL with MIGS (CPT 66989, 66991): 91.4%
- Retinal Detachment with Vitrectomy (CPT 67108, 67113): 92.4%

These findings were slightly lower but consistent with the most-recently-available Medicare claims data showing these procedures are primarily delivered in an ASC or HOPD facility.

[3] https://iorpartners.com/why-ior/about/

Those respondents who indicated that they did not currently perform these procedures in the office were then asked to indicate why they have not yet embraced the use of an office surgical suite for each procedure type. Respondents were allowed to select multiple answer options, or write-in their own reasoning.

The top three barriers to adoption of office-based surgery were consistent across procedure types: patient safety concerns, lack of office-based accreditation standards/certification for the procedure, and a lack of Medicare coverage in the office setting. The Academy expands on these concerns below and would be happy to meet with CMS to discuss the survey results in further detail if requested.

Office-Surgery Patient Safety/Efficacy Concerns

Extrapolation of Existing Patient Data

The Academy feels strongly that there is a need for published, peer-reviewed evidence addressing the safety of these procedures in a private practice office setting outside of a large healthcare system such as Kaiser Permanente prior to their valuation by CMS in a non-facility setting. Because Medicare reimbursement would effectively invite widespread expansion of office-based surgery for these procedures, the data must be representative of the provider subspecialist and Medicare beneficiary populations that would gain access to ophthalmic–office surgery should non-facility pricing be implemented.

We look forward to peer reviewed publication of the safety data iOR Partners shared with the Academy, as well as evidence that the data are generalizable to ophthalmic private and academic practices of various sizes. We are concerned that the typical ophthalmology practice interested in launching an in-office surgical suite would not be required to or financially incentivized to solicit outside expertise during implementation. Given the significant training and staff support iOR Partners provides the physician practices it has contracted with, resulting safety and outcome data points may not be representative of what can be achieved by the typical physician practice caring for Medicare beneficiaries.

Similar concerns exist with the Kaiser study data referenced in the nominator's original submission to CMS. The Kaiser network is an exceptionally large, well-funded integrated network of physicians servicing its own limited network of patients in a cluster of US states. The Kaiser data found that office-based ophthalmic surgery can be

performed safely under appropriate conditions, but it is not generalizable to the typical ophthalmology practice or patient experience in other health insurance programs.

In both circumstances, the Academy cannot reasonably endorse the assumption that the above findings on patient safety/outcomes will persist through a nationwide expansion of office-based cataract, MIGS, and retinal/vitrectomy procedures. We anticipate additional data on safety, adverse events, and costs will continue to be published studying representative populations; we encourage CMS to review these data before recommending office-based valuation for these procedures.

Office-Suite Certification & Accreditation Standards

We agree with CMS's statement in the proposed rule:

> *These codes are complex surgical eye procedures and they require dedicated spaces, similar to facility-based spaces that are not typically found in an ophthalmologist's office, such as a well-lighted and sterile surgical theater, specific eye surgery equipment and possibly clinical staff and other medical personnel trained to assist in these surgeries and the patient's immediate post-surgery recovery*.

These as well as additional standards for ophthalmic surgery need to be maintained regardless of surgical setting. While we believe it is possible to achieve such conditions in a non-facility setting that is properly constructed and maintained for appropriate infection prevention and control, CMS currently has no requirements regulating the construction, maintenance, and sterility of office-based surgical suites. Unlike HOPD or ASC settings, there are no Conditions of Participation/Coverage for the physician's office.

In our cursory review, we found that state-level office surgical facility accreditation requirements vary from state to state and can differ from ASC guidelines. Moreover, the vast majority of ophthalmology offices lack accreditation by one of the major accrediting agencies (i.e., American Association of Ambulatory Surgical Facilities, Accreditation Association for Ambulatory Health Care, and The Joint Commission). Whether office procedures are performed with or without an anesthesia care provider, as discussed below, a range of concerns have been identified, including perioperative management, complication management, and patient recovery.

Non-patient-related issues include the possibility of unqualified physicians performing procedures outside of their scope of practice/skill set due to absence of facility credentialing, the potential for substandard facilities and/or difficulty recruiting and training qualified surgical suite personnel. We have additional concerns regarding the availability of backup vitrectomy instrumentation in the office suite, as these instruments are very sophisticated and may fail sufficiently often that backup capacity is necessary. Redundant instrument capacity is routine in ASC and HOPD settings due to facility size and case volumes, protecting patient safety and outcomes.

Use of Anesthesia

We applaud CMS in its proposed 2023 rule noting the need for "a well-equipped, fully-staffed medical facility" including anesthesia services, for cataract and retinal detachment surgery. Patients currently undergoing these procedures are typically sedated in addition to the administration of a local or topical anesthetic. Regardless of age, many patients would not tolerate cataract surgery performed solely with topical or intracameral anesthetic.

When undergoing cataract or cataract with MIGS surgery, the eyelids are retracted with an eyelid speculum and the anterior segment is surgically entered to remove and replace the patient's clouded crystalline lens. Cataract/IOL with MIGS and vitrectomy procedures are lengthier than stand-alone cataract procedures, with greater risks of patient discomfort, movement, and infection due to surgical site contamination during the procedure. Special attention is necessary to ensure that Medicare beneficiary satisfaction in terms of quality, comfort, and safety is maintained.

Patient Selection Criteria

Another issue of concern includes that of patient and procedure selection. In previous rulemaking discussing office-based ophthalmic surgery, CMS stated that "routine cases in patients with no comorbidities could be performed in the non-facility surgical suite, while more complicated cases (for example, pseudoexfoliation) could be scheduled in the ASC or HOPD." This may not be easily accomplished.

Factors that make cataract extraction more complex are not always known in advance of the surgery. Ophthalmologists, regardless of how thoroughly they screen patients, must always be prepared for unusual findings or complications, which can arise before, during, or after the

surgery. It is critical to have the proper resuscitation equipment including a crash cart and the surgical devices and drugs necessary to manage a complication immediately available.

Any comorbidities that require a higher level of anesthesia personnel should necessitate performing the procedure in the facility setting. Certain cardiovascular complications would require immediate transfer of care to a facility setting and it would be important for the proper protocols and arrangements to be in place prior to development of a complication requiring urgent or emergent higher-level care. While these situations may be infrequent, this is an important patient safety consideration given the high utilization of cataract procedures. Physicians may also not have the ability to access all three types of facilities.

COVID-19 and Other Projected Care Backlogs

The nominator suggested that office-surgery could solve a COVID-19 related backlog for cataract and retinal services. It will take several years to implement office-based Medicare reimbursement, presumably well past the peak of the COVID-19 (PHE) and its impact on Medicare beneficiaries. Additionally, the projected 38.5 million cataracts by 2050, suggested by the nominator, appears to be in-line with total-population growth trends, as well as growth in demand for physician services generally. The Academy expects to arrive at such cataract-volumes gradually, and that the U.S. health care delivery system is positioned to grow to meet this capacity over time.

Both in absolute terms and relative to the other nominated cataract/MIGS codes, CPTs 67108/67113 are exceptionally low-volume procedures. Given claims-volumes' implications for Medicare patient-need of any given procedure, the Academy notes reservations regarding the suggestion that CPTs 67108/67113 sustainably create the utilization necessary to justify significant upstart-investments in new office surgical suites.

We believe CMS is in the best position to analyze current Medicare claims volumes and confirm that a surgical backlog or unprecedented future demand exists. **We encourage CMS to confirm whether surgical backlog is a current issue before making decisions about providing reimbursement for OBS based on this assumption.**

Payment for office-based surgery for these procedures would not increase the number of retina, glaucoma, or other relevant subspecialists

available to deliver these nominated procedures. Nor do proposals for expansion of ophthalmic office surgical suites require or offer economic incentives to locate potential new sites of service in currently underserved communities.

The history of past physician practice expansions indicates that market forces make it likely that future office-based surgical ventures will primarily target population-dense metropolitan areas with well-established markets for physician services, rather than underserved areas where investment is riskier. While this longstanding concern is not specific to ophthalmic medicine or office surgical suites, neglecting to address it while continuing with this potential expansion as suggested by the nominator would likely exacerbate rural-urban disparities in care access.

Similarly, the Academy is concerned that costs required to launch an office based surgical suite will exert further pressure on physician practices to consolidate into larger well-capitalized organizations. While we support private equity and hospital-led efforts to meet expanding patient needs, such market-dominating organizations hold strong negotiating power when contracting with private payers, creating opportunity for unintended impacts on the overall reimbursement landscape.

In summary, the primary reasons why ophthalmologists are concerned about office-based surgery are patient safety, lack of office-based accreditation standards/certification for the procedure, and a lack of Medicare coverage in the office setting. **While the Academy is optimistic for the future of ophthalmic-office surgical suites and the potential these facilities will offer for increased patient convenience, increased physician control of scheduling, and availability of OR time for urgent cases, at this time we cannot support its nationwide expansion without additional peer-reviewed studies including patient safety and outcome data for these nominated procedures.** We also need to see plans to standardize office surgical suite certification and accreditation standards, in line with those for an ASC; and ideally, a roadmap to bring office-suites to communities that most need these physician services.

Payment for Medicare Telehealth Services

CMS is proposing to continue paying for services placed temporarily on the telehealth list through the end of 2023. Broadly, the Academy has

been supportive of proposals to expand telehealth coverage especially during the PHE when in-person visits have been particularly challenging. The Academy thanks and supports CMS' proposal to add ophthalmological service codes, CPTs 92012 and 92014, to its covered telehealth services list.

Valuation of Specific Codes

RUC Process and Integrity

For CY 2023, CMS has proposed accepting only 75% of the total Relative-value Update Committee (RUC) recommendations. AAO believes that the Medicare program benefits from the consensus effort at the RUC by all medical specialty societies and health insurers. The RVS Update Committee is the best representation of a House of Medicine evaluation. The RUC process is thorough with ample opportunities for deliberation, negotiation, and adjudication. It is the work of this dedicated volunteer community of physicians who contribute time, energy and knowledge that make the RUC process a success that benefits the Medicare program and all practicing physicians by maintaining relative values between services. Medical societies, such as the Academy, expend significant resources and expense to gather data and bring their recommendations forward. This process involves the review of data from statistically valid survey instruments, thorough vetting, and discussion both within the specialty's clinical and valuation experts as well as the broader panel who have a thorough understanding of the time and intensity components of a service's value. **We urge CMS to continue working with the RUC as it is the most representative consensus of all medical specialties.**

Specific Ophthalmology Codes and Values

Orthoptic Training – CPT 92065, 920XX

We appreciate CMS' proposal to accept the RUC-recommended work values and direct practice expense inputs for CPT 92065, *Orthoptic training; performed by a physician or other qualified health care professional* and CPT 920XX, *Orthoptic training; performed by a physician or other qualified health care professional under supervision of a physician or other qualified health care professional*. The recognition of these as two separate services more accurately describes and values them.

Dark Adaptation – CPT 92284

CMS disagreed with the RUC-recommended work value of 0.14 for CPT 92284, Dark adaptation examination with interpretation and report and the RUC-recommended crosswalk to CPT 76514, Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness). CMS proposed several alternative work values based on several different rationales and methodologies, none of which we agree with.

CMS found that the reduction in the RUC-recommended work value did not reflect the reduction in physician time noted in the surveys. However, the existing intraservice time of 36 minutes was Harvard-based and has never been presented to the RUC. During the first five-year review, the work value was reduced from 0.37 to 0.24, but the times and work values for the service were not surveyed and there was no RUC review of physician time. This de-linked the current relationship between time and work value for CPT 92284. Further, it is well-known and accepted that Harvard times and values correlate very poorly to current practice and should never be used when making relative value comparisons. Use of the reduction in physician time compared with a Harvard value, and the existing value of CPT 92284 in particular, is flawed methodology.

CMS noted that 92284 is typically provided with an E/M visit on the same day and used this to further reduce the proposed value. However, the RUC-recommended valuation took the performance of a same-day office visit into account for its recommendation and reduced the pre- and post-service times from the survey times of 5 and 10 minutes respectively to 1 minute each. The pre- and post-service work does not include formulating a differential diagnosis or discussing results of the test with the patient because these activities would be part of a same-day office visit. The pre-service time of 1 minute is necessary to explain the test to the patient and enter the order into the electronic health record (EHR). The post-service time of 1 minute is necessary to sign the report, enter the results into the EHR, and add the results to the letter to the referring physician. None of these activities are part of the same-day office visit. The RUC has reduced pre- and post-service times for services performed with a same-day office visit to 1 minute for many testing services, and CMS has accepted these times. Rejecting them now would interfere with the relativity maintained in the RVS system.

CMS noted that the physician work largely consists of interpreting machine-generated results. We and the RUC agreed and reduced the surveyed intraservice time of 15 minutes to 3 minutes. This represents a change in technology which allows technicians to administer the test, a change with which most survey respondents were not familiar. The 3-

minute estimate of intraservice time is based on recommendations of the expert panel with input from clinicians familiar with the use of the newer technology. We know of no more valid source of a time estimate. Due to the change in technology, this code has been placed on the New Technology list and will be reviewed in 3 years. At that time if claims have increased and the automated test technology has penetrated the marketplace to a greater extent, a resurvey will generate more accurate time data. Until then, any other estimate of physician time is pure speculation and unlikely to be as accurate as the RUC-recommended, expert-based value.

One of CMS' proposed work values for CPT 92284 is zero, with comparisons to several ophthalmic screening tests (CPT 99172 and 99173). Dark adaptation is not a screening test. It is performed for evaluation of patients with existing pathology, most commonly age-related macular degeneration, or one of several retinal degenerations, including congenital stationary night blindness. The code is being referred to CPT for an editorial revision to include the word "diagnostic" in the code descriptor to reduce the potential for confusion with screening tests. There is physician work associated with performing and interpreting the test, and its value is certainly greater than zero.

CMS also suggests a work value of 0.06 RVU based on a reverse building block methodology but offers no details as to how this very low value was derived. Reverse building block is not an ideal valuation methodology. It is typically used when neither a magnitude estimation of work nor a crosswalk can provide a reasonable value which maintains relativity within the RVS.

In this case, the RUC-recommended crosswalk to CPT 76514 *Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)* is reasonable and is based on time estimates from those familiar with the newer technology. It is supported by the high degree of similarity between the survey respondents' time and intensity of work estimations for CPT 92284 and CPT 76514. The recommended work value of 0.14 RVU therefore maintains relativity with other procedures. The service will be placed on the New Technology list and reviewed in 3 years to address any further change in physician work. We therefore strongly recommend that CMS accept the RUC-recommended work value of 0.14 RVU for CPT 92284.

CMS also proposes reducing the direct PE input for the lens set (EQ165) and motorized table (EF030) from 24 minutes to 15 minutes, citing the time that the equipment is in use during performance of the test (CA021). In addition to that time, the equipment is unavailable for use

during the following activities, all of which occur in the testing room, and which take 9 minutes:

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

These activities all occur in the room with the testing equipment, lens set, and table, making them unavailable for use with another patient. The standard default equipment formula was used and RUC practice expense direct input benchmarks for clinical staff time were used for CA011, CA013, CA014, and C024. The input time for CA016 was reduced from the benchmark of 2 minutes to 1 minute because no intravenous access is required for this test. However, 1 minute was retained because that time is required for initial positioning and monitoring of the patient prior to beginning the test protocol. It is standard practice to include this time associated with the service that the equipment is unavailable when calculating direct PE inputs. Not including these inputs for this one code while including them for all other codes using the standard default equipment formula would alter the relativity of services within the RVS. Therefore, the times for CA011, CA013, CA014, CA016, and CA024 should be included when calculating the time for the lens set (EQ165) and motorized table (EF030). The 9 minutes detailed above, when added to the 15 minutes of CA021, results in the 24 minutes recommended by the RUC. We ask that CMS include this time in the direct PE input for CPT 92284.

Anterior Segment Imaging, Fluorescein Angiography – CPT 92287

We agree with CMS and thank them for proposing to accept the RUC-recommended work values and direct PE inputs for CPT 92287, *Anterior segment imaging with interpretation and report; with fluorescein angiography*.

Quantitative Pupillometry – CPT 959XX

CMS disagreed with the RUC-recommended work value of 0.25 RVU. This value was based on the survey 25th percentile magnitude estimation of work. It was further supported by CPT 72190, *Radiologic examination, pelvis; complete, minimum of 3 views* with pre-, intra-, and post-service time of 1/5/1 minutes which exactly matched the survey median times and an exactly matching work value of 0.25 RVU.

CMS' disagreement was partially based on a comparison to the survey key reference service CPT 92081, Visual field examination, unilateral or bilateral, with interpretation and report; limited examination (e.g., tangent screen, Autoplot, arc perimeter, or single stimulus level automated test, such as Octopus 3 or 7 equivalent). The surveyed physicians who chose CPT 92081 rated it equivalent in intensity and complexity to the surveyed code 959XX. Arguably, that supports the RUC-recommended value given that the difference in intraservice times is only 2 minutes. However, less than half of the survey respondents chose CPT 92081, making it an unreliable comparator. The RUC chose not to use the key reference service due to the small percentage of respondents that chose it and the inaccuracy inherent in comparing intraservice work per units of time (IWPUTs) among codes with short intraservice times.
Instead, CMS proposes a work RVU of 0.18 with a crosswalk to CPT 92504, *Binocular microscopy (separate diagnostic procedure)*. The service that the RUC used to support the recommended work value, CPT 72190, is a better match to CPT 92287 for the following reasons:

First, the pre-, intra-, and post-service times for CPT 92504 (2/5/2) do not match the survey median and RUC-recommended times (1/5/1), which CMS has not challenged. The times for the RUC-recommended support code CPT 72190 (1/5/1) match the survey respondents' median times exactly.

Second, CPT 92054 was last valued in 2010 while CPT 72190 was last valued in 2019. Valuations over 10 years old are typically considered to be less relevant than more recent valuations. The survey for CPT 72190 (54 respondents) was also more robust than that for CPT 92054 (31 respondents).

Furthermore, CMS' proposed value of 0.18 work RVU ignores the survey magnitude estimation of work. The survey's 25th percentile work value was 0.25 RVU and was the primary basis for the RUC-recommended value. Surveyed 25th percentile work value estimates are an accepted and commonly used valuation method which supports relativity within the RVS.

The perfectly matching 25th percentile survey estimate of work value and the perfectly matching time and work values for CPT 72190 are strong indicators that a work value of 0.25 RVU is correct and will maintain relativity within the RVS. We urge CMS to adopt the RUC-recommended work value of 0.25 RVU for CPT 959XX.
We appreciate the proposal to accept the RUC-recommended direct PE inputs for CPT 959XX.

Remote Retinal Imaging AI – CPT 92229

We appreciate CMS' continuing reimbursement of CPT 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral*), rather than having carrier pricing. This new and groundbreaking technology has great public health potential. It offers the promise of extending early detection of diabetic retinopathy to underserved populations at their point of medical care, and with that the opportunity to significantly reduce preventable vision loss among Medicare beneficiaries with diabetes.

We appreciate that CMS recognizes that practitioners incur resource costs for ongoing use of the software necessary to provide this service. The analysis fee is a direct practice cost analogous to a supply because it is attributable to a specific imaging service provided to a specific patient each time it is performed. It is not an indirect cost like computer hardware or software that is purchased once or licensed annually or monthly and then utilized repeatedly to provide varying services to multiple patients.

CMS has an excellent opportunity to improve access to this sight-saving technology which improves screening of diabetics for serious and visually-disabling disease by supporting separate payment for CPT 92229 in Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs). There is precedent for this policy because glaucoma screening (HCPCS G0117 and G0118) can be reimbursed as a stand-alone billable visit for FQHCs and RHCs if no other services are furnished on the same day.[4] In addition, the Medicare Outpatient Prospective Payment System (OPPS) assigns CPT 92229 to Ambulatory Payment Classification (APC) 5733 (Level 2 Minor Procedures) with a status indicator of "separate payment".

2021 Phased-in Cuts: Strabismus and Canaloplasty

Strabismus Surgery - CPT 67311, 67314, 67320, 67331, 67332, 67334, and 67340

Allowable fees for the entire family of strabismus surgery codes were reduced substantially in 2021. The seven services noted above suffered greater than 20% cuts and were phased in, with 19% reductions taken in

[4] Centers for Medicare & Medicaid Services. (2021, April 26). *Medicare Benefit Policy Manual Chapter 13 - Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services.* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c13.pdf

2022 and additional reductions scheduled for 2023. Four of the services (CPT 67320, 67331, 67332, and 67334) were reduced so drastically that they will again have to be phased in, with 19% cuts in 2023 and additional cuts in 2024.These procedures are all designed to correct ocular misalignment by removing one or more extraocular muscles from their insertions, shortening or repositioning the extraocular muscle, and resuturing it to the sclera.

While we appreciate that CMS adopted the RUC recommendations for the family of eleven strabismus surgery codes (CPT 67311-67340) we are concerned with the impact of these dramatic reductions in a very short time period made worse by the COVID-19 PHE. **We feel strongly that the reductions for these services should be phased in more gradually to mitigate the potential impact on access to care associated with such large reductions primarily affecting children.** Even with a phase-in, these represent major cuts to almost all the surgical codes used by pediatric ophthalmologists, a limited and shrinking group of physicians who are the major providers of these services. Therefore, we also recommend that the phase-in be implemented over an additional three years, with one third of the remaining reductions taken annually rather than a 19% reduction in 2023 and the remainder in 2024. We are aware of reports from our members of delayed access for patients in need of these unique services.

The CMS budget impact of these prolonged phase-ins will be minor because of the small Medicare FFS claims volumes. However, it will be significant for the pediatric ophthalmologists who perform these procedures primarily on children covered by Medicaid and commercial insurance.

Dilation of Aqueous Outflow Canal – CPT 66174, 66175

We note that CPT 66174, Transluminal dilation of aqueous outflow canal; without retention of device or stent and CPT 66175, Transluminal dilation of aqueous outflow canal; with retention of device or stent are scheduled for phase-in practice expense adjustments based on their reduced valuations last year. We would like to take this opportunity to disagree with CMS' assigned work values once again for these services, which were lower than the RUC-recommended values.

CMS assigned a work value of 7.62 WRVU for CPT 66174 as opposed to the RUC-recommended value of 8.53, and a work value of 9.34 WRVU for CPT 66175 compared with the RUC-recommended value of 10.25.

CMS proposed a work RVU of 9.34 for CPT 66175 "using a reverse building block methodology" but did not describe what CPT codes or work values were used to arrive at that value. We are therefore unable to specifically comment on the methodology CMS used.

We agree that the RUC-recommended values and times place these two codes near the top of the intensity and complexity spectrum of surgery, which is appropriate for intraocular procedures involving 360-degree microscopic cannulations of Schlemm canal, a structure with a diameter of less than 20 microns in the typical glaucoma patient. In addition, we are concerned with CMS' choice of CPT 15150 as an upper limit to support their proposed values. This skin-graft procedure is much less intense and complex than an intraocular procedure and carries an IWPUT of 0.0237, far lower than any other intraocular procedure.

Instead, we urge CMS to reconsider the RUC-recommended work value of 10.25 WRVU for CPT 66175. This value is supported by two recently valued procedures with identical intraservice times (ISTs) of 30 minutes, CPT 67110 and CPT 66982. These procedures have similar total times which bracket the total time for CPT 66175. The IWPUTs of these two comparator codes also appropriately bracket that of CPT 66175, recognizing that the intensity of an intraocular procedure is greater than that of a skin graft.

We appreciate that CMS accept the underlying methodology used by the RUC to arrive at the value for CPT 66174, agreeing that the only difference between this and CPT 66175 is the additional intraservice time associated with placement of the stent in the canal. We agree with CMS and with the RUC that the incremental work value is 1.72 WRVU, derived by subtracting the difference between the survey 25th percentile work values for CPT 66174 and CPT 66175.

We recommend that CMS retain this 1.72 WRVU increment and apply it to the RUC-recommended work value for CPT 66175, recognizing the intensity of the intraocular work. Therefore, we request that CMS adopt the RUC-recommended value of 8.53 WRVU for CPT 66174.

If CMS moves forward to reduce the RVUs assigned to CPT 66174, the Academy requests that CMS phase-in the proposed rate reduction over the next three years. As highlighted above, phasing cuts in smaller increments can mitigate the negative access effects on access to care and lessen disruption of clinical treatments for glaucoma. We strongly encourage CMS to adopt a phase-in period longer than 2 years for any further potential reduction to CPT 66174, as the CMS has adopted in prior circumstances for significant procedure rate changes.

The Academy appreciates CMS working to ensure all communities and beneficiaries have access to innovative sight-saving technology.

Evaluation and Management (E/M) Visits

We continue to be disappointed that CMS has declined to apply the 2021 E/M increases to post-operative visits in the global surgical payment. Denying an equitable increase for post-operative visits in the global period is equivalent to reimbursing some providers more than others for the same work. We, along with other surgical groups, supported the original RUC proposed increase in payment for E/M codes with the understanding that post-operative visits in the global surgical payment would also receive the same increase. The RUC has carefully vetted the service level of post op care typically suggesting 99212 and 99213. **We urge CMS to apply E/M increases to post-operative visits in the global surgical payment in the CY 2023 final rule.**

Rebasing and Revising the Medicare Economic Index (MEI)

In an effort to better reflect current market conditions, CMS proposes to rebase and revise the Medicare Economic Index. The current MEI weights are based on data obtained from the AMA's Physician Practice Information (PPI) Survey, which was last conducted in 2007/2008 and collected 2006 data. The agency plans to rebase the MEI using 2017 data from the United States Census Bureau's Service Annual Survey (SAS). While we agree with the agency that the MEI base data is out of date, we feel an update of the AMA's PPI Survey is more consistent and reliable because it is sourced directly from practices. **We understand that the AMA is already engaged in an extensive effort to update the PPI Survey and ask that CMS pause consideration of other sources of cost data for use in the MEI until the AMA effort is complete and evaluated.**

Changes to the MEI would have far-reaching effects, including specialty redistribution, aggregate PE cost pool redistribution, and geographic redistribution via the Geographic Practice Cost Index (GPCI). Therefore, we appreciate the agency collecting public feedback and the clarification that CMS does not plan to implement the new weights in 2023. We believe updated base data is critical to accurately modifying payment component weights. **We agree with the agency's decision to wait until base data is updated to redistribute payment weights and**

encourage CMS to use the results of the updated AMA PPI Survey instead of the SAS. We appreciate CMS's recognition of the changing costs of providing care, particularly the expenses associated with technology. **Once the baseline data are updated, the Academy could be supportive of shifting more weight to the PE component of MEI. A more moderate or phased-in change than that proposed in the rule would lessen the disruption to medical practice.**

Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Since 2017, CMS has required the use of a JW modifier to identify and pay for discarded amounts of drugs on claims for separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B. The agency has noted that sometimes no JW modifier is billed and questions whether there is no discarded drug or if the modifier is being omitted in error. To collect more accurate data, CMS is proposing a new modifier, JZ, to indicate that no amount from a single use vial or single use package was discarded.

The Academy believes this new requirement creates an unnecessary burden for ophthalmologists and urges CMS to consider alternatives. Most ophthalmic single-use vial or single-use package drugs are used completely in the provision of care. For instance, they are not adjusted by patient weight as might be for many injectables. Therefore, requiring use of a JZ modifier would be an additional *purely administrative* step for ophthalmology practices. Rather than adding administrative burden to physicians, we encourage CMS to consider ways to use claims data already being collected. Alternatively, CMS could exempt drugs that never have discarded amounts from being subject to rebate. These drugs would not need a JW or JZ modifier.

We also have concerns for how Medicare Administrative Contractors would implement JZ modifier edits in their claims processing systems, because edits typically happen on a claim-line level. A drug code claim line could be missing a JZ modifier because it is accompanied by another drug code claim line with a JW modifier. It is unclear how claims processing logic could be programmed to avoid incorrect claims rejections.

As of January 1, 2023, the law requires all manufacturers to reimburse CMS 106% of the ASP of all discarded drug minus 10%. Certain types of

drugs are statutorily excluded from the definition of "refundable single-dose container or single-use package drug"; however, we do not feel these exclusions are adequate to address the unique circumstances of many ophthalmic drugs.

By design and/or function, drugs with volumes less than 1 mL per vial already have very little or no drug that is discarded. For example, ten percent of a 0.9 mL bottle would be nine hundredths of a milliliter (0.09 mL), which is between 1 and 2 drops of liquid. It is impossible clinically to draw into a syringe such minute volumes and not have more than this amount remaining in the vial or wasted due to dead space in the syringe. It is unnecessary and unfair to impose rebate requirements on drugs where the wasted amount is insignificant or in many cases of small-volume drugs, necessary to insure delivery of the required dose. The 10% threshold for withdrawing medication from a vial for fulfilling CMS reimbursement could lead manufacturers to provide smaller vial volumes, resulting in insufficient drug being drawn into the syringe and under-dosing of patients. The fill would be simply too small to allow accurate withdrawal of medication from the vial.

Drugs with weight-based dosing should also be considered for exemption because the rebate requirement creates bias in favor of treatment of patients with a higher body surface area compared to patients with a lower body surface area. For example, when treating a patient with high body surface area, there may be no discarded amount, but for a patient with low body surface area, there may be considerable wastage. Manufacturers cannot be expected to produce multiple vials with differing amounts of drug to account for multiple different patient weights, as this would certainly increase overall costs.

For each of these unique circumstances, we are concerned that future innovation could be discouraged and access to treatment inhibited. We understand that CMS is statutorily limited in the exclusions from the definition of "refundable single-dose container or single-use package drug." We therefore recommend that the agency use its statutory authority to raise the wastage threshold applicable to the rebate requirement for the unique circumstances described above. For drugs with volumes less than 1 mL per vial, the Academy recommends a 100% threshold: essentially an exemption for these low-volume drugs. For weight-based dosage drugs, a reasonable applicable percentage would consider the range of weight treated and consider the weight of the smallest person being treated, considering the excess beyond that true wastage.

Specific Issues in the Medicare Quality Payment Program

Proposed Modifications to Previously Finalized Specialty Measures Sets

The Academy has significant concerns with the proposal to add "Optometry" to the title of the Ophthalmology specialty set. CMS is proposing this change due to feedback from "interested parties" and overlap in the denominator eligible patient populations of both specialties. However, this type of "regulatory" combination of the two specialties could lead to providers who lack the knowledge, licensure, or experience necessary to differentiate the care expected from each group of doctors as well as confuse policymakers and beneficiaries about the specialties. Basing this proposal on an overlap in denominator eligibility, adds to our concern about the understanding of the differences between ophthalmologists and optometrists. While some overlap may exist, currently optometrists serve a much younger population, many of whom are not close to qualifying for Medicare. We are concerned that placing non-surgical optometrists in the same category as ophthalmologists will blur the distinctions between the two different specialties. Based on our experience with licensure issues at the state level, we feel strongly that this change would have serious implications for inappropriate expansion of the scope of procedures for which optometrists may seek reimbursement. **The Academy has grave reservations with this proposed amalgamation of the two distinct specialties into one set of measures, due to the possible risks and harms this may cause to patients following implementation.** The speed at which this proposal appears to be moving forward magnifies the Academy's concerns. We would like an opportunity to discuss the significance of this change in greater detail prior to any further action.

MIPS Value Pathways

Timeline

The Academy appreciates CMS acknowledging the need for stability in the traditional MIPS program. In order to establish a period of consistency for reimbursement requirements, we agree that maintaining the current thresholds and weighting levels for traditional MIPS is critical. Practices are still experiencing uncertainty from the ongoing

PHEs and CMS long-term plans to transition to MVPs will be a dramatic change for ophthalmologists under the MIPS program.

Although CMS's proposal provides no firm timeline on the sunsetting of traditional MIPS, the agency indicates its clear intent to replace MIPS with MVPs at some point in the future. At this time, ophthalmologists and many other physicians do not have an MVP option available. In addition, ophthalmologists have limited alternatives since they do not fit into most Alternative Payment Models (APMs). If the agency continues this transition to MVPs without the option for traditional MIPS, ophthalmologists and other physicians will be left without a reporting method to avoid penalties. **If CMS were to move forward with eliminating traditional MIPS, the Academy would need more information on how CMS plans to handle clinicians that lack available MVP or APM pathways for reporting and what CMS plans to do to make it possible for these clinicians to avoid penalties**.
We feel strongly that participation in a QCDR that is providing prompt feedback and benchmarking outcomes to physicians should be a standalone qualifying pathway for MIPS.

Additionally, the Academy seeks clarification about the goal of the MVP reporting option and how it advances CMS' aim to improve quality or transition clinicians into APM participation as originally intended. Though several MVPs have been introduced and codified, we are still concerned that the concept remains vague and the pathway to testing MVP effectiveness lacks clarity. The MVP program, in its current state, mimics the traditional MIPS program with a few changes. However, it does not provide elements specific to APM participation that allow clinicians to become familiar with the requirements of a given APM.

If the traditional MIPS program is terminated at some undefined future point and clinicians are pushed to participate in APMs, participation in an MVP does not make them more prepared to do so than they are today. As an effective transition stage into the APM program rather than MVPs, CMS should develop a program or element in an existing program that delivers participants regular and relevant feedback on cost metrics that prepares clinicians to take on financial risk.

The future transition away from traditional MIPS gives CMS an opportunity to reconsider the recognition of EHR-based clinical data registries as a pathway towards demonstrating value. Participation in an EHR-based Qualified Clinical Data Registry (QCDR) provides real time, relevant feedback to clinicians who actively monitor their activity. QCDRs allow clinicians to compare themselves with national and inter-practice benchmark reports on their performance related to clinical care

and patient outcomes relevant for their specialty and subspecialty. QCDRs help physicians monitor and manage patient populations, facilitating early interventions and preventive care, which can lead to more successful disease management and less expensive care.[5] Clinician-led QCDRs collect specialty-specific meta-data that can be used to analyze treatment effectiveness in specific demographics, at specific stages in the disease process, and account for variables in a way that was not previously possible. This could allow researchers and clinicians to better identify and treat underserved communities which aligns with the Administration's and CMS' goal of improving equity in health care. Additionally, end-to-end electronic transfer of data shows real-world evidence of interoperability and contribution of health information to advance public health goals set by CMS.

The Academy believes instead of advancing multiple overly complicated value-based payment programs, physicians should be rewarded for participating in a CMS-approved EHR-based QCDR which allows self-evaluation. Numerous published articles criticizing MIPS have recommended that CMS recognize clinical data registry participation instead. Such a move is also aligned with the Congressional MACRA directive encouraging the use of registries. In fact, encouraging use of registries can be expected to advance clinical health care.

Quality Performance Category Scoring

The Academy continues to support CMS' proposal to use existing benchmarks and believes that creating new benchmarks for MVP participants could unfairly disadvantage clinicians in the traditional MIPS program by crediting them with fewer points for being further along in the topped-out measure lifecycle. In addition, for specialties and clinicians that do not have MVPs available to them, it would be unfair to provide benefits to performance scoring for which they are not eligible.

Quality Performance Category

Proposed Removal of Quality Measures

For the 2023 performance year (PY), CMS has proposed the removal of 15 quality measures. This is a substantial number of measures proposed

[5] Rich WL 3rd, Chiang MF, Lum F, Hancock R, Parke DW 2nd. Performance rates measured in the American Academy of Ophthalmology IRIS Registry (Intelligent Research in Sight). Ophthalmology. 2018; 125:782-784.

for removal and will have significant consequences for practices attempting to avoid payment penalties in CY 2025. While the Academy appreciates that measures being removed are not going to have a significant impact on our patients or providers, we still want to flag our caution on removing a significant number of measures like this. Clinicians need to be able to report measures that are clinically appropriate and for many practices, especially those in small, rural practices, the removal of quality measures can inhibit their ability to reach the minimum measure requirement. Even large practices with EHRs will see a negative impact depending on the specialty or subspecialty.

Without measures that span specialties and corresponding subspecialties and which can be collected without EHR, CMS is disadvantaging small and rural practices that are providing necessary care for patients.

Additionally, because of the ongoing COVID-19 PHE, measure developers, qualified clinical data registries, medical societies, and others have had to delay measure development and testing. **With the possibility of CMS removing measures from the program and organizations unable to test and offer new measures to alleviate the strain for practices, at a minimum, CMS should delay the removal of MIPS quality measures for one year.** This will allow QCDRs time to provide their users with better options. This will also allow a grace period for practices still feeling the grave effects of the PHE such as lowered patient volumes, shortages of staff, financial difficulties, and diminished administrative help that are needed to navigate the loss of longstanding MIPS quality measures. With the penalty at 9%, this is a weighty threat to practices that are trying to remain open during the pandemic and would cause severe financial stress that could cause them to pull away from Medicare or close their practices.

We have concerns that the Measure Set Review process does not provide adequate opportunity for public feedback, particularly from measure stewards. With only a 5-business day window to submit comments, the ability to gather and provide meaningful feedback on the removal of measures is significantly limited. Even if an organization or individual does have the time to fully articulate their thoughts in this short time span, the limited information they are provided makes it extremely difficult to provide meaningful feedback.

With these problems in the existing feedback process and the significant negative impacts that removing measures can have on providers, the **Academy urges CMS to exercise its authority when**

deciding whether to remove or retain measures in all the quality reporting programs. In particular, we encourage CMS to consider how removing measures could adversely affect the ability of providers to meaningfully participate in the Quality Payment Program.

New Measures

CMS is seeking feedback on the potential addition of two new measures to establish a measure on screening for social drivers of health as a new quality measure. The Academy supports this proposal and thanks CMS for continuing to support the addition of these measures to the QPP.

Data Completeness

The Academy supports CMS proposal to maintain the current data completeness threshold at 70% for PY 2023. For practices without an EHR, it is extremely burdensome to meet the data completeness threshold manually and the Academy appreciates CMS' efforts to not increase burden for these practices. However, in PY 2024 and PY 2025, CMS is proposing to increase the data completeness threshold to 75%. It seems unlikely that such an increase would improve the statistical validity of the data. The Academy requests the rationale for increasing the data completeness threshold as well as the data on which CMS is basing this decision.

Raising the data completeness threshold could impact both manual reporters and EHR reporters alike. While most EHR practices report 100% of the data collected for a calendar year, those who are changing EHRs or practices during a reporting year often are unable to report for the full year and the lower threshold allows them to report without being penalized. Incomplete data can be attributed to multiple factors such as timing of the change for the EHR vendor or practices, and contractual issues with EHR vendors or physician relationships with prior practices.

The American Academy of Ophthalmology's IRIS® Registry has experienced these issues firsthand, as some practices have switched EHR systems after our internal deadline for mapping. This leaves the IRIS Registry and practices in a position where the balance of pulling data quickly and ensuring data integrity can be very difficult. As much leniency from CMS in these situations is appreciated and by maintaining a lower data completeness threshold, CMS is providing more leniency to both the vendors and practices involved in these transitions.

Quality Measure Scoring

Removal of 3-point Floor

Beginning with PY 2023, CMS is removing the 3-point floor for measures that do not meet the case minimum (except for small practices). **The Academy supports this proposal and thanks CMS for maintaining leniency for small practices that often have difficulty achieving higher quality scores.**

Removal of Bonus Points

For PY 2023, CMS is implementing last year's proposal to remove bonus points for reporting additional outcome and high-priority measures and the end-to-end reporting bonus.

The removal of bonus points will discourage the use of EHR reporting and outcome measures, contrary to the direction that CMS have been advancing practices towards for years. As the MIPS program gets harder, practices need more assistance in achieving the threshold to avoid a penalty. With the elimination of bonus points even high-performing practices previously succeeding in MIPS will struggle to earn an incentive or even avoid a penalty.

The ability to offer clinicians an incentive to report measures through end-to-end reporting sets vendors, such as QCDRs furthers the goal of the program and provides more useable real-world data. These end-to-end electronic reporting bonus points and bonus points for outcome and high-priority measures also encourage clinicians to sign up with QCDRs. **The Academy urges CMS to reconsider the previously finalized policy to remove high priority and outcome measure bonuses and the end-to-end electronic reporting bonus.**

Cost Performance Category

Experience Report: Cost Measure Performance Transparency

We ask CMS to provide transparency on cost measure performance. We would ask that this report includes any trends on services or coding which cause variation in the cost measure score. Currently, practices are provided with no usable feedback on cost measure performance that allows them to make real-time or future changes to improve. Without

having a mechanism for feedback or seeing results as a part of the ongoing MIPS process throughout the year, practices do not have the tools to make adjustments until the annual process ends. If CMS were to provide timely cost measure performance transparency, practices may be more willing to participate in APMs with shared risk. More experience and understanding of how practitioner's actions affect cost performance is critical to the success in the APM portion of the QPP.

Promoting Interoperability (PI) Performance Category

Public Health and Clinical Data Exchange Objective

The Academy supports CMS' implementation of the Immunization Registry Reporting measure and the Electronic Case Reporting measure unless an exclusion is claimed at the provider level. Additionally, we support the allocation of bonus points for the Clinical Data Registry Reporting measure, the Public Health Registry Reporting measure, and the Syndromic Surveillance Reporting measure. However, the PI category and this measure objective should align with congressional intent to incentivize registry reporting. **Further registry reporting outside of the proposed required measures should be worth ten or more bonus points to encourage the use of registry reporting.**

Performance Threshold/Payment Adjustment

In PY 2023, CMS is proposing to maintain the performance threshold at 75 points. Without the continued funding for the exceptional performance threshold, that aspect and the additional bonus that came with it are no longer included to support providers who are exceeding expectations. While we are glad to see that there will likely be a bigger bonus pool due to fewer exclusions, we would appreciate more detailed information on how different specialties and practices would be impacted. **The Academy appreciates CMS projecting future payment adjustment amounts, which gives societies a stronger argument for their membership as to why clinicians should continue to fully participate in MIPS.**

Additionally, the Academy would like to highlight our concern over ending the exceptional performance bonus. Especially during the uncertainty and financial challenges currently posed by the ongoing PHE, this additional funding has been critical to recognizing high performance achieved by our providers. As flagged in the proposed rule, we share CMS's concerns that with providers shifting out of

Advanced APMs and the expectation that there will be an unintended significant impact on the distribution of the overall MIPS payment pool. While we understand that the funding must remain overall budget neutral, we would still request that CMS work toward alternative means to continue improving and supporting this part of the program. We encourage CMS to work with Congress on a solution to restore the exceptional bonus pool.

QCDR Measure Testing

The Academy appreciates all our conversations with CMS regarding the issue of QCDR measure testing and CMS' willingness to listen to our concerns. QCDRs have limited resources, especially following the PHE, and need adequate time and guidance from CMS to ensure success. **In light of the ongoing PHE and the overall difficulties with implementation, the Academy supports CMS's decision to continue to delay full measure testing for QCDR measures for an additional year.** This is critical while specialty societies and other QCDR vendors recover financially and shift back to priorities outside of the PHE, but also does not address the longer-term concerns the Academy has with the current process. Currently, full testing is required to begin for the 2024 QCDR submission process. Regarding QCDR measure testing, the Academy supports the proposals previously provided by the Council of Medical Specialty Societies (CMSS). Specifically, we echo the suggestions that CMS:

- Offer incentives to clinicians and practices that participate in measure testing (e.g., bonus points, automatic credit for improvement activities (IA).
- Acknowledge that QCDRs could be allowed to demonstrate some empirical assessment of new measures for initial data testing requirements.
- Provide funding to encourage measure development and testing, particularly to be responsive to the need to address disparities and promote health equity.

The Academy requests that CMS provide clarification and guidance on what testing will be required to satisfy the QCDR testing requirements. It would be beneficial for QCDRs and measure stewards to be able to review testing protocols with CMS prior to testing to ensure that CMS will approve to avoid wasted expenses. Because of the looming measure testing requirements, many societies have dropped or are considering dropping QCDRs qualification for their registries, leaving many specialists without clinically relevant measures. **Without additional incentives to support implementation, QCDR development is likely to face significant challenges beyond the issues created by the PHE.**

Extreme and Uncontrollable Circumstances (EUC) Hardship

The Academy supports CMS continuing to offer the optional EUC hardship for practices affected by the COVID-19 pandemic. However, we believe continuing automatic hardship exemptions disincentivizes MIPS participation. In our IRIS® Registry we have seen a decline in participation correlating with the application of automatic exemptions. Although the COVID-19 pandemic continues to affect some practices across the country in terms of patient volume, staffing, and financial issues, this has not been uniform across all medical practices. **Thus, an automatic extreme and uncontrollable circumstances hardship exception is not appropriate for the 2022 reporting year.**

Alternative Payment Models

The Academy has concerns with CMS' approach to APMs. While past incentives for clinicians to participate in APMs were clear—a 5% bonus, MIPS exemption - CMS has not provided reasonable pathways to participate. APMs have not been a viable pathway for ophthalmology, particularly for subspecialists, and now that the bonuses have ended the narrow viability path has closed even further.

Most existing APMs are focused on primary care or hospital-based care which does not allow for ophthalmologists' and other specialists' participation. Since there is not a direct path for many specialty clinicians to participate in APMs, resources should be dedicated to designing and implementing models that are inclusive of clinicians outside of hospitals. CMS Quality staff could work closely with the Centers for Medicare & Medicaid Innovation (CMMI) and specialty societies to develop models that fit the needs of a given specialty.

Although there are few opportunities for specialists to participate in APMs, the Academy believes that APM participation will see significant decline unless Congress extends the **5% annual bonus incentive for physicians to develop and participate in Advanced APMs.** These bonuses were only authorized by MACRA through the 2022 performance year. Specialists who have not been afforded the opportunity to participate have been disadvantaged.

Additionally, as the push to transition from one system to another continues, it is important to ensure that there is a robust educational effort targeting affected providers. Between increased educational

efforts on MIPS reporting and specific attention being paid to those shifting to APMs or in the long term from MIPS to MVPs, this kind of support from CMS is critical to ensure the process moves as smoothly as possible for all parties.

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In conclusion, we appreciate the opportunity to comment on the Medicare Program; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amount proposed rule. The Academy is committed to protecting sight and empowering lives by setting the standards for ophthalmic education and advocating for our patients and the public. If you have questions or need any additional information regarding any portion of these comments, please contact Brandy Keys, MPH, Director of Health Policy at bkeys@aao.org or via phone at 202-587-5815. Again, the Academy would like to thank you for providing us with the opportunity to comment and to work with CMS. We look forward to ongoing engagement and stakeholder input.

Sincerely,

Michael X. Repka, MD, MBA
Medical Director, Governmental Affairs
American Academy of Ophthalmology

David B. Glasser, M.D.
AAO Secretary for Federal Affairs
AAO RUC Advisor

Appendix A. Examples of Post-operative Visit Medical Decision Making for Select Ophthalmic Procedures

Procedure Codes: 66984, 66982

Xcapsl Ctrc Rmvl Insj Io Lens Prosth W/O Ecp; Xcapsl Ctrc Rmvl Insj Io Lens Prosth Cplx Wo Ecp

Number and level of postoperative visits included in current valuation:

66982

- 1 visit: 99212
- 3 visits: 99213

66984

- 1 visit: 99212
- 2 visits: 99213

The visit levels were based on prior code level selection criteria dependent upon the number of history and physical exam elements performed. The current E/M criteria no longer include the number of history and physical exam elements performed. Current code level selection is based on either medical decision making (MDM) or time and must be supported by medical necessity Therefore, the code level assignments for the postoperative visits no longer conform to code level selection criteria.

The following analysis is based on current MDM and medical necessity criteria for E/M code level selection.

Review of the post-operative visits:

1. The 1-day post-op visit's purpose is to ensure that the wounds are Seidel negative and that the intraocular pressure is within a reasonable limit. Typically, both are the case, but the level of complexity shoots up if not. Dilation is typically deferred on the 1-day post-op visit. Medications are reviewed, instructions are reviewed, the patient is again instructed on safety post-operatively.
2. The 1-week post-operative visit's purpose is to rule out endophthalmitis. By definition, that means looking at the anterior and posterior vitreous, which is best done with pupillary dilation. It is a very frequent occurrence that patients describe photopsias which are most often lenticular, but it is important to confirm that the retinal periphery is not damaged. The pre-operative work then done to prepare the patient for the second case, if contralateral eye surgery is needed, is separately billable, and the work done is inherently different and not duplicative.

3. The 1-month post-operative visit's purpose is to obtain a final refraction and confirm the absence of post-operative cystoid macular edema, or peripheral retinal pathology and that the patient did well with the initial medication taper and doesn't need an extended taper. Pupillary dilation is needed again on this visit.

Typical post-operative billing based on a typical patient:

1. Number and/or Complexity of Problems Addressed at the Encounter (99213):
    a. Low: 1 stable chronic, or 1 acute uncomplicated: Depending on how one defines the follow up for cataract surgery, the visits may be listed as either 1 acute uncomplicated problem (recent cataract surgery that was successful with a diagnosis of nuclear sclerosis, cortical cataract, or posterior subcapsular cataract), or 1 stable chronic condition (nuclear sclerosis, cortical cataract, or posterior subcapsular cataract). Neither problem is "self-limited" as without proper management, neither will resolve on its own without intervention. Not operating will lead to progressive vision loss (cataract is the leading cause of blindness in the world), and patient non-compliance can lead to serious vision loss from uveitis, macular edema, posterior synechiae threatening pupillary block, iris bombé, and acute glaucoma.
2. Amount or/or Complexity of Data to be Reviewed and Analyzed (99212):
    a. Minimal or none: tests such as OCT macula may be performed, but these are separately billable as thus not counted.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management: (99213)
    a. Moderate: Prescription drug management is performed at every visit in the post-op period changing the dosages of steroids and adding or adjusting medications in the immediate post-operative or later post-operative periods to adjust for pressure elevations (due to retained viscoelastic in the 1 day or steroid response hypertension in the later visits as needed), corneal edema, epithelial defects, post-operative keratitis, dry eye, and other issues.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded; thus **99213 would be justified** in the E/M system. All three visits meet these criteria.

Procedure Code: 67108

Pars Plana Vitrectomy for Repair of Retinal Detachment

Number and level of postoperative visits included in current valuation:

- 5 visits: 99213

The visit levels were based on prior code level selection criteria dependent upon the number of history and physical exam elements performed. The current E/M criteria no longer include the number of history and physical exam elements performed. Current code level selection is based on either medical decision making (MDM) or time and must be supported by medical necessity Therefore, the code level assignments for the postoperative visits no longer conform to code level selection criteria.

The following analysis is based on current MDM and medical necessity criteria for E/M code level selection.

Review of the post-operative visits:

1. Number and/or Complexity of Problems Addressed at the Encounter (99213):
    a. Low:1 stable chronic, or 1 acute uncomplicated
    b. Depending on how one defines the follow up for a retinal detachment repair, a diagnosis of retinal detachment can be listed as either 1 acute uncomplicated problem, or 1 stable chronic condition (*at the very minimum*). During these visits a dilated exam would need to be performed to ensure there is no post operative infection, inflammation, and most importantly that the retina remains attached. These exams are typically tougher than standard exams as we are looking through a gas bubble to make many of these observations.
2. Amount or/or Complexity of Data to be Reviewed and Analyzed (99212):
    a. Minimal or none: tests such as OCT and Fundus photos may be performed, but these are separately billable as thus not counted.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management (99214):
    a. Moderate: Prescription drug management is performed at every visit in the post op period by adjusting the dosages of steroid (with known complications of intraocular pressure changes (IOP), etc), dilation, and antibiotics medications. In fact, one of the reasons for the number of visits is to

monitor for IOP fluctuations throughout the post op process. Consequently, many additional medications such as IOP drops, with their associated side effects, can be required to control such changes.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded; thus, **99213 would be justified** in the E/M system.

Procedure Code: 67113

Pars Plana Vitrectomy for Repair of Complex Retinal Detachment

Number and level of postoperative visits included in current valuation:

- 6 visits: 99213

The visit levels were based on prior code level selection criteria dependent upon the number of history and physical exam elements performed. The current E/M criteria no longer include the number of history and physical exam elements performed. Current code level selection is based on either medical decision making (MDM) or time and must be supported by medical necessity Therefore, the code level assignments for the postoperative visits no longer conform to code level selection criteria.

The following analysis is based on current MDM and medical necessity criteria for E/M code level selection.

Review of the post-operative visits:

1. Number and/or Complexity of Problems Addressed at the Encounter (99213):
    a. Low:1 stable chronic, or 1 acute uncomplicated
    b. Depending on how one defines the follow up for a retinal detachment repair, a diagnosis of retinal detachment can be listed as either 1 acute uncomplicated problem, or 1 stable chronic condition (*at the very minimum*). During these visits a dilated exam would need to be performed to ensure there is no post operative infection, inflammation, and most importantly that the retina remains attached. These exams are typically tougher than standard exams as we are looking through a gas bubble to make many of these observations.
2. Amount or/or Complexity of Data to be Reviewed and Analyzed (99212):
    a. Minimal or none: tests such as OCT and Fundus photos may be performed, but these are separately billable and thus not counted.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management (99214):
    a. Moderate: Prescription drug management is performed at every visit in the post op period changing the dosages of steroid (with known complications of intraocular pressure changes (IOP), etc), dilation, and antibiotics medications. In fact, one of the reasons for the number of visits is to

monitor for IOP fluctuations throughout the post op process. Consequently, many additional medications such as IOP drops, with their associated side effects, can be required to control such changes.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded; thus **99213 would be justified** in the E/M system.

Procedure Codes: 66170

Trabeculectomy ab externo

Number and level of postoperative visits included in current valuation:

- 4 visits: 99212
- 5 visits: 99213

The visit levels were based on prior code level selection criteria dependent upon the number of history and physical exam elements performed. The current E/M criteria no longer include the number of history and physical exam elements performed. Current code level selection is based on either medical decision making (MDM) or time and must be supported by medical necessity Therefore, the code level assignments for the postoperative visits no longer conform to code level selection criteria.

The following analysis is based on current MDM and medical necessity criteria for E/M code level selection.

Review of the post-operative visits:

1. Number and/or Complexity of Problems Addressed at the Encounter (99213):
    a. Low:1 stable chronic, or 1 acute uncomplicated
    b. A diagnosis of glaucoma is usually one stable chronic condition or one chronic condition with progression. During postoperative visits an exam would need to be performed to ensure there is no post operative infection, to assess the level of inflammation, and to ensure the bleb remains watertight without leaks.
2. Amount or/or Complexity of Data to be Reviewed and Analyzed (99212):
    a. Minimal or none: typically, tests are not performed or analyzed at these visits.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management (99214):
    a. Moderate: Prescription drug management is performed at every visit in the postoperative period, adding antibiotics, adjusting the dosages of steroid according to the severity of bleb inflammation, and adding or removing cycloplegics depending on the presence of hypotony or inflammation. Additional decisions and interventions are made at postoperative visits, including laser suture lysis of subconjunctival flap sutures and subconjunctival injection of steroids and/ or antifibrotic medications. These injections

are billable, while suture lyses are not separately paid during the global period.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded; thus, 99213 would be justified for each of the nine postoperative visits under the current E/M system.

Procedure Codes: 66172

Trabeculectomy ab externo with scarring from previous ocular surgery or trauma

Number and level of postoperative visits included in current valuation:

- 6 visits: 99212
- 5 visits: 99213

The visit levels were based on prior code level selection criteria dependent upon the number of history and physical exam elements performed. The current E/M criteria no longer include the number of history and physical exam elements performed. Current code level selection is based on either medical decision making (MDM) or time and must be supported by medical necessity Therefore, the code level assignments for the postoperative visits no longer conform to code level selection criteria.

The following analysis is based on current MDM and medical necessity criteria for E/M code level selection.

Review of the post-operative visits:

1. Number and/or Complexity of Problems Addressed at the Encounter (99213):
    a. Low: 1 stable chronic, or 1 acute uncomplicated
    b. A diagnosis of glaucoma is usually one stable chronic condition or one chronic condition with progression. During postoperative visits an exam would need to be performed to ensure there is no postoperative infection, to assess the level of inflammation, and to ensure the bleb remains watertight without leaks.
2. Amount or/or Complexity of Data to be Reviewed and Analyzed (99212):
    a. Minimal or none: typically, tests are not performed or analyzed at these visits.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management (99214):
    a. Moderate: Prescription drug management is performed at every visit in the postoperative period, adding antibiotics, adjusting the dosages of steroid according to the severity of bleb inflammation, and adding or removing cycloplegics depending on the presence of hypotony or inflammation. Additional decisions and interventions are made at postoperative visits, including laser suture lysis of

subconjunctival flap sutures and subconjunctival injection of steroids and/ or antifibrotic medications. These injections are billable, while suture lyses are not separately paid.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded; thus **99213 would be justified** in the E/M system for each of the 11 postoperative visits.

Procedure Code: 65756

Keratoplasty (corneal transplant); endothelial

Number and level of postoperative visits included in current valuation:

- 3 visits: 99212
- 3 visits: 99213

This number of postoperative visits was based on a robust survey (51 respondents) and was confirmed by the RUC and accepted by CMS. The visit levels were based on prior code level selection criteria dependent upon the number of history and physical exam elements performed. The current E/M criteria no longer include the number of history and physical exam elements performed. Current code level selection is based on either medical decision making (MDM) or time and must be supported by medical necessity Therefore, the code level assignments for the postoperative visits no longer conform to code level selection criteria.

The following analysis is based on current MDM and medical necessity criteria for E/M code level selection.

1. Number and/or Complexity of Problems Addressed at the Encounter: Low (99213)
    a. Low: 1 stable chronic, or 1 acute uncomplicated illness or injury
        i. Patients for whom endothelial keratoplasty is performed have endothelial dysfunction causing visual disability. Common causes are endothelial dystrophy or secondary endothelial dysfunction. In most cases this represents an exacerbation or progression of a single chronic illness or side effect of treatment, which would qualify as “moderate” for the number and/or complexity of problems addressed.
        ii. After surgery, patients continue to have chronic underlying illness(es) or side effect of treatment (endothelial dystrophy or secondary dysfunction) that led to the need for surgery. Successful surgical replacement of the corneal endothelium renders the status of the underlying disease stable, making the number and/or complexity of problems “low” if there are no complications or additional comorbidities that need to be addressed during the postoperative visit. Many of these patients do have additional

comorbidities For this analysis it is assumed that they do not.

iii. During the postoperative period, patients without complications also have an acute, uncomplicated illness or injury related to the surgical intervention. Those who develop complications would qualify as "moderate" based on one or more chronic illnesses with exacerbation, progression, or side effects of treatment. However, most patients have an uncomplicated postoperative course, with the number and/or complexity of problems remaining "low" throughout the postoperative course.

2. Amount or/or Complexity of Data to be Reviewed and Analyzed: Minimal or None (99212):
    a. Minimal or None: typically, tests are not performed or analyzed at these visits.
3. Risk of Complications and/or Morbidity or Mortality of Patient Management: Moderate (99214):
    a. Moderate: Prescription drug management is performed at every visit in the postoperative period. This includes adding or discontinuing topical antibiotics, adjusting dosages of topical corticosteroids according to the severity of intraocular inflammation and the risk and/or presence of graft rejection, and adding or removing cycloplegics depending on the presence of hypotony or inflammation.
    b. Additional decisions and interventions made during postoperative visits include assessment of the need for graft rebubbling the anterior chamber or repositioning the corneal graft. These interventions are infrequently performed and are separately billable.
4. Medical necessity
    a. Every one of the six postoperative visits is crucial to supporting a successful outcome. The presence, absence, and the risk of developing graft dehiscence or dislocation, infection, inflammation, and/or immunologic rejection and the level of intraocular pressure must be frequently assessed by history and physical examination.
    b. Medical decision making to address each of these by maintaining or adjusting topical medications and determining the need for additional intervention as well as determining the interval for future monitoring based on current status occurs during each of the postoperative visits.

Summary: To qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded. Therefore, 99213 would be justified in the E/M system for each of the six postoperative visits included in the global period for CPT 65756, *Keratoplasty (*corneal *transplant); endothelial*.