

September 6, 2023

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

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

Dear Administrator Chiquita Brooks-LaSure:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing 6,500 ophthalmologists in the United States and abroad who share an interest in cataract and refractive surgical care. We appreciate this opportunity to provide comments on the 2023 Medicare Physician Fee Schedule (MPFS) proposed rule, which includes the Quality Payment Program (QPP) and the Merit-Based Incentive Payment System (MIPS).

Below is an executive summary of our comments and recommendations:

#### MEDICARE PHYSICIAN FEE SCHEDULE

#### 2023 Proposed Conversion Factor

- ASCRS continues to be concerned about the growing financial instability of the MPFS. Annual Medicare physician payment cuts are unsustainable, especially for solo and small practices struggling to provide patient care due to rising inflation costs, workforce shortage issues, and the financial effects of the COVID-19 public health emergency (PHE). In order to address the instability of the MPFS that plagues physicians with annual reimbursement cuts, ASCRS urges CMS to not only work with Congress to address the impending cuts scheduled to take effect next year, but to find a long-term solution as well to create stability for physicians participating in the Medicare program. In addition, we urge CMS to ask Congress to provide an inflationary update to the Medicare conversion factor in calendar year (CY) 2023 and beyond.
- The payment disparity between physicians and other Medicare providers is inexcusable and can no longer be ignored. CMS proposes cutting Medicare payments to physicians by 4.5% in CY

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2023 in response to statutory requirements and regulatory changes. When combined with the 4% Pay-As-You-Go (PAYGO) cut, physicians face an 8.5% cut come January 1, 2023. Meanwhile, other Medicare providers expect to see a significant increase in payments in CY 2023, for example:

- MA plans will receive an 8.5% payment increase.
- Inpatient hospitals will receive a 4.3% payment increase.
- Rehabilitation facilities will receive a 3.9% payment increase.
- Hospices will receive a 3.8% payment increase.
- And hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) will receive a 2.7% payment increase.
- Despite diagnosing, treating, and managing patients' health, physicians face an 8.5% payment cut. These payment disparities are unacceptable, and ASCRS calls on CMS to address physician reimbursement disparities immediately to ensure that beneficiaries can continue to access timely care.
- Therefore, ASCRS urges CMS to work with Congress to reduce the Medicare physician payment cuts scheduled to take effect on January 1, 2023, due to the 4.51% reduction to the conversion factor that will impact all physicians and potentially threaten patient access to care. For CY 2023, CMS proposes a MPFS conversion factor of \$33.0775, a decrease of approximately 4.51% (\$1.53) from the CY 2022 MPFS conversion factor of \$34.6062. The CY 2023 proposed MPFS conversion factor reflects a budget neutrality adjustment of 1.55% and the expiration of the 3% payment increase for all services for CY 2022 provided by the *Protecting Medicare and American Farmers from Sequester Cuts Act*, which mitigated the impact of the CY 2022 budget neutrality cuts. The majority of these cuts were a result of the CY 2021 MPFS, where CMS increased the standalone evaluation and management (E/M) codes billed mainly by primary care but did not apply those same increases to the corresponding E/M post-operative codes included in the 10-and 90-day global surgical codes billed by specialty physicians. Regrettably, CMS did not propose any changes to this policy in the CY 2023 MPFS proposed rule that would address this issue, and we urge the agency to do so and apply those increases to surgical post-operative visits.

#### Potentially Misvalued Services Under the PFS: Cataract Surgery and MIGS

- ASCRS acknowledges that the flexibility of location for patients and convenience of scheduling
  cataract surgery for providers who are not able to perform the surgery in an ophthalmic ASC are
  potential benefits to performing cataract surgery codes (65820, 66174, 66982, 66984, 66989,
  and 66991) in a non-facility setting. However, ASCRS cautions CMS and urges it to evaluate all
  possible patient safety issues and other potential complications before creating a non-facility
  payment for cataract surgery codes.
- We have concerns regarding patient safety, the possibility of complications, and the use of anesthesia when performing cataract surgery in a non-facility setting. CMS should be aware that

office-based surgery may not be appropriate for many cataract patients, especially those that qualify as complex cataract cases. The vast majority of cataract patients are elderly, with comorbidities, and may have multi-systemic diseases. These types of conditions increase potential complications, especially when anesthesia is administered. Furthermore, the surgeon may not be aware of certain complications until the surgery has been initiated.

 ASCRS maintains that infection prevention and control standards that apply to the ASC and HOPD sites of services would need to be established and applied to non-facility settings. We are concerned with the current lack of certification requirements and oversight of office-based surgical settings. To guarantee appropriate infection prevention and control and regulation of in-office surgical suites at both federal and state levels, CMS would need to develop standards and certification requirements.

## Policies Related to Evaluation and Management (E/M) Codes

- ASCRS is extremely disappointed that CMS continues not to incorporate the revised E/M values that were implemented on January 1, 2021, to the 10- and 90-day global surgical codes. CMS speculates that the visits captured within the global surgical payment are not typically performed, which it maintains is supported by analysis conducted by the RAND Corporation. However, this is not the case for cataract surgery. Not only were the cataract surgery codes resurveyed in 2019, revalued through the AMA/Specialty Society RVS Update Committee (RUC) process, and accepted by CMS; but the RAND study, which analyzes claims-based reporting data, also confirmed that cataract surgeons are providing 3 post-operative office visits. Furthermore, the CY 2022 MPFS final rule reaffirmed the values of the cataract codes. Therefore, it is not appropriate for CMS to continue to choose not to provide equity to the cataract surgery codes. We urge CMS to implement the increases that were applied to the standalone E/M codes to the 10- and 90-day global cataract surgical codes, as their values have recently been confirmed by the AMA RUC, CMS, the RAND studies, and claims-based reporting data.
- CMS is arbitrarily devaluing surgical post-operative visits and disrupting the relativity of the
  MPFS by not applying equity to the 10- and 90-day global surgical codes. CMS recognized the
  importance of maintaining relativity in the fee schedule after the RUC reviewed and
  recommended increases to discrete E/M codes and global codes in 1997 (after the first five-year
  review), in 2007 (after the third five-year review), and in 2011 (after CMS eliminated consult
  codes and moved work RVUs into the office visit codes). By not applying these increases, CMS is
  distorting the relativity of the fee schedule and creating inequities among physicians.
- ASCRS maintains that the best way to determine the value of a typical post-operative surgical
  visit is to rely on the AMA RUC and the AMA Relativity Assessment Workgroup (RAW). If CMS
  does not believe post-operative E/M services in the global period are occurring, we recommend
  CMS send them to the RUC for reevaluation. At a minimum, for all 10- and 90-day global surgical
  codes that have been recently revalued and confirmed by CMS, like the cataract surgical codes,
  the agency should adjust the E/M payment immediately to reflect the updated payment
  increases applied to the standalone E/M codes that were implemented on January 1, 2021.

## 10- and 90-Day Global Surgical Services

- ASCRS reiterates our strong opposition to CMS' policy that will not apply the 2021 increased values of standalone E/M services to the post-operative E/M visits in 10- and 90-day global surgical codes for CY 2023. CMS implemented RUC-recommended increases to standalone E/M services for CY 2021 and other select bundled services and codes but is not following the RUC's recommendation to extend those increases to global surgical post-operative services. In the CY 2023 proposed rule, CMS continues to ignore our comments that by applying this update to standalone codes, and other additional codes, the policy violates the Medicare statute by creating a specialty payment differential and impacts the relativity of the Medicare physician fee schedule.
- ASCRS urges CMS to adjust the cataract values of the E/M post-operative visits included in 10- and 90-day global surgical codes to reflect the updated E/M standalone code payment increases that were implemented on January 1, 2021. The cataract codes' values were also reaffirmed in the CY 2022 MPFS Final Rule. Since CMS accepted the values of the cataract codes, which include 3 post-operative visits, there is no reason that ophthalmologists should not be paid at the same level E/M visit payments as other physicians when they provide the same level of service per patient.

#### 66174 and 66175 Dilation of Aqueous Outflow Canal

- ASCRS strongly disagrees with the work value of 7.62 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 published in the CY 2022 MPFS Final rule. ASCRS urges CMS to accept the RUC-recommended work value for these procedures.
- If CMS moves further with additional reductions to CPT code 66174, we urge it to apply a phasein period longer than two years for any further reductions. ASCRS is extremely concerned by the
  significant rate reduction to CPT 66174, and that it may potentially affect access for
  beneficiaries and disrupt clinical treatments. To mitigate these adverse consequences that may
  impact patient care, we request that CMS phase in further rate reductions over the next three
  years.

## <u>Telehealth</u>

- ASCRS supports CMS' proposed expansion of the Medicare Telehealth Services list on a
  permanent basis, CMS' proposal to further expand the Medicare telehealth services list on
  temporary (Category 3) basis, and CMS' proposal that all Public Health Emergency (PHE)
  allowances for telehealth last for 151 days after the PHE ends.
- ASCRS urges CMS to continue allowing audio-only E/M services (99441-99443) by keeping them on the Medicare Telehealth Services List after the end of the PHE and the 151-day post-PHE

extension period. In the absence of telehealth platforms, local broadband infrastructure, and financial resources, audio-only services have made telehealth more accessible to Medicare beneficiaries. Since cataracts are primarily an aging disease, there are many older cataract patients who lack the technical knowledge and capability to utilize more traditional telehealth methods like video communication technology. It is also likely that many Medicare beneficiaries may not have access to video communication platforms. CMS will be doing a disservice to the Medicare beneficiary population if they move forward with removing audio-only services.

ASCRS urges CMS to recognize the significant education and financial investments that practices
have made to expand access to telehealth services by providing additional guidance that clearly
defines supervision requirements, as well as state scope of practice and licensing, and any
applicable state or local laws, to help better ensure the quality of care for telehealth services.

# <u>Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to</u> <u>Provide Refunds with Respect to Discarded Amounts</u>

- ASCRS has concerns with CMS' proposal to use a new modifier, JZ, to indicate that no amount from a single\_use vial or single-use package was discarded, as it creates an unnecessary burden for ophthalmologists.
- ASCRS also urges CMS to exempt ophthalmic drugs by using its statutory authority to raise the wastage threshold to 100% for drugs with volumes less than 1 mL per vial.

#### Medicare Economic Index (MEI)

- ASCRS supports CMS' recognition that the data currently used for the MEI is outdated and needs
  to be revised, but we believe the AMA should complete its data collection project for practice
  cost before CMS considers using other outdated data. The AMA has informed CMS that it is
  engaged in an extensive effort to collect updated practice cost data from physicians. We support
  the collection of this data, and we urge CMS to pause considering other sources of cost data for
  use in the MEI until the AMA has completed its data collection effort.
- CMS' proposal to update the MEI weights using 2017 data from the United States Census Bureau's Service Annual Survey (SAS) would cause significant flaws in its estimates. Most importantly, the proposal would significantly redistribute Medicare dollars from "physician work" to "practice expense," diminishing physicians' specific contribution to the health care system.

## **QUALITY PAYMENT PROGRAM**

MIPS Value Pathways (MVPs) - Opposition to Mandatory MVPs and Sunsetting of MIPS

• While CMS has developed 7 new MVPs and is proposing that MVPs be available gradually, beginning with the 2023 performance year, the intent is to eventually sunset traditional MIPS after the end of the 2027 performance period. CMS further indicates that they are not proposing the timeframe in which MVP reporting would no longer be voluntary and the future sunset of MIPS in this proposed rule, but a proposal to sunset MIPS as we know it would be made in future rulemaking. ASCRS continues to oppose any effort to make MVPs mandatory. We believe that physicians and practices should continue to have options, including the ability to continue to participate in MIPS. A physician, not CMS, is best positioned to determine which measures are appropriate for their practice and patient population. Furthermore, forcing specialty physicians, like ophthalmologists, to report on mandatory MVPs would subject them to problematic population-health measures, which we reiterate have nothing to do with the specialty of ophthalmology or the care that is provided.

## Certified Electronic Health Record Technology (CEHRT): 2015 Edition Cures Update

- We strongly urge CMS to monitor the progress of EHRs receiving the Cures Update certification.
- We also ask CMS to ensure that clinicians using an EHR vendor that does not meet the deadline for the Cures Update have access to the Medicare Promoting Interoperability Program (PI) decertification hardship exception for the 2023 reporting year.

## <u>Proposed Modifications to Previously Finalized Specialty Measures Sets</u>

ASCRS has significant concerns with the proposal to add "Optometry" to the title of the
Ophthalmology specialty set. This "regulatory" combination conflates the difference between
the two specialties in regards to education, clinical knowledge, and licensure as it relates to the
treatment of patients. We urge CMS not to move forward with adding Optometry to the
Ophthalmology specialty set.

#### **Opposition to Elimination of Topped-Out Measures**

In general, ASCRS continues to oppose the elimination of "topped-out measures." We maintain
that the continued reporting and measurement of these measures is important, and that CMS
should continue awarding credit for maintaining high quality. It is important to note that high
performance rates do not mean that a measure is no longer meaningful to a particular patient
population or specialty and should stop being reported.

#### Review of the Cataract Surgery Episode-Based Cost Measure

ASCRS remains concerned that the cataract surgery episode-based cost measure disincentivizes
the use of drugs that are separately paid to promote a policy priority, such as the pass-through
payment policy and the non-opioid pain management exclusion to packaging drugs used during
surgical procedures. Therefore, we ask CMS to consider suspending the use of this measure in
MIPS as it undertakes a full review of the measure and its specifications. ASCRS continues to

believe that pass-through drugs and drugs excluded from packaging under the non-opioid pain management exception should not be included in the cataract cost measure. In both cases, policymakers have concluded that separate reimbursement outside of the packaging is warranted to promote a defined policy priority. Because the current cataract cost measure creates a financial disincentive to use drugs that are included in the measure's specifications, the measure is inconsistent with the payment decision to unpackage such products. We have heard from our members that the increasing value of the Cost component in the MIPS score makes it difficult to use these separately reimbursed products. Until the Wave 1 cost measure review is complete, and this issue addressed, ASCRS urges CMS to consider suspending the cataract surgery episode-based cost measure to eliminate the disconnect with the payment policies that support the use of pass-through and/or non-opioid pain management drugs.

# **Measures and Scoring**

- As indicated above, we oppose the removal of so-called "topped-out" ophthalmology measures. In general, we continue to oppose CMS' topped-out measure methodology and recommend continuing to award credit for maintaining high quality. We also request CMS suspend topped-out measure scoring caps for 2023 due to the PHE.
- **Promoting Interoperability (PI) category.** We continue to recommend that physicians using a qualified clinical data registry that is fully integrated with their EHR system should be awarded full credit in this category.

## Advanced Alternative Payment Models (APMs)

ASCRS continues to support the development of specialty-specific Advanced APMs, as current
models are primary care-based and may not be appropriate for specialists, such as
ophthalmologists, or encourage their participation. We encourage the Center for Medicare and
Medicaid Innovation (CMMI) and CMS to prioritize models for testing or implementation that
have been recommended by the Physician-Focused Payment Model Technical Advisory
Committee (P-TAC) and specialty physician organizations.

#### Full comments on these issues are below:

# **MEDICARE PHYSICIAN FEE SCHEDULE**

I. Potentially Misvalued Services Under the MPFS: Cataract Surgery Codes

ASCRS appreciates the opportunity to comment on the merits of continuing to value the cataract codes only in the facility setting. When CMS issued a Request for Information in the 2016 MPFS proposed rule on cataract surgery performed in a non-facility setting, ASCRS surveyed its membership for feedback to aid in developing our comments. Similarly, we issued a survey to our members to guide our response to

the CY 2023 MPFS proposed rule, requesting comments on creating non-facility values for the cataract surgery codes. Cataract surgeons in the United States continue to respond in a similar manner as they did previously when asked about performing the procedure in a non-facility setting. While we acknowledge there may be some potential benefits to developing a non-facility payment, there are continued concerns that would need to be addressed regarding patient safety and the possibility of significant complications, including anesthetic, pulmonary, and cardiac issues. Furthermore, CMS has not established standards for the construction, maintenance, sterility, or oversight of office-based surgery, which poses safety and sterility risks for patients.

## **Patient Safety and Possible Complications**

ASCRS maintains that patient safety is of the utmost importance, and we urge CMS to take all possible factors into account before establishing a non-facility payment for cataract surgery. In the proposed rule, CMS notes that the nominator suggests that "cataract and retinal procedures can be properly performed in the non-facility office, safely, effectively, and perhaps more conveniently for patients and physicians." To our knowledge, there are no peer-reviewed studies that support this claim. It is imperative that patient safety be a priority, and there should be sufficient data to support that cataract surgery in an office-based setting can be as effective and safe as cataract surgery performed in a hospital outpatient department (HOPD) setting or Ambulatory Surgery Center (ASC).

CMS should be aware that office-based surgery may not be appropriate for many cataract patients, especially those that qualify as complex cataract cases. The vast majority of cataract patients are elderly, with co-morbidities, and may have multi-systemic diseases. It is known that in the elderly population, there is a greater risk of having pulmonary, cardiac, or hypertension complications, which can complicate a 'routine' cataract procedure if the patient is not properly monitored and treated immediately. Sometimes, complications during cataract surgery are predictable (i.e., patients with a pre-existing condition or history of trauma to the eye). However, complications from cataract surgery can arise unexpectedly, and all surgeons must be prepared to deal with these complications to prevent vision loss for the patient.

In some situations, surgeons may not know if a particular patient will be a complicated case until after the surgery has begun. It is also possible that even the slightest movement from a patient during surgery can cause surgical complications. For example, a patient may cough during surgery, which causes them to move suddenly. This movement can lead to the complication of posterior capsule rupture and subsequent vision loss. At this moment, the surgeon will take longer than usual to perform the procedure, necessitating a change in anesthesia protocol. In addition, several other pieces of equipment, including a vitrector and different intraocular lens, will likely be needed. This complication puts the patient at higher risk for cystoid macular edema, endophthalmitis, retained cataract fragments, vitreous traction, retinal detachment, displaced intraocular lens (IOL) position, and a host of other sight-threatening complications. Due to the possibility that what is predicted to be a standard, routine surgery can end up with a vision-threatening complication in a split second, it is essential that all settings where cataract surgery is performed are equipped to handle complicated and non-complicated cataract procedures.

We also want to remind CMS that as part of cataract surgery, intravenous (IV) sedation is commonly used in conjunction with local anesthesia in order to improve the patient's surgical experience and

cooperation. Some patients require more than topical and/or IV sedation in order to provide them with the optimal environment in terms of procedural safety and best outcomes, as well as optimizing safety as it relates to the general health and well-being of the patient. Additionally, these patients are generally older, have multiple medical conditions, as well as comorbidities, and require regular monitoring of vital signs and the capability to undergo deeper anesthesia whenever necessary. Monitoring during the administration of anesthesia and surgery generally includes using a cardiac monitor, pulse oximeter, and measurement of blood pressure and respiration. It is essential that these monitoring actions are performed by personnel other than the operating ophthalmologist. Furthermore, surgeons typically employ drugs such as epinephrine or phenylephrine, which have cardiac effects, including arrhythmias. There is also an oculocardiac reflex that causes a slowing of the heart rate for some patients, which can lead to serious cardiac events. These issues illustrate that intraocular surgery with anesthesia remains an intensive surgery with significant risks. To ensure patient safety and the best outcomes, it is paramount that qualified personnel, such as anesthesiologists or Certified Registered Nurse Anesthetists (CRNAs), monitor and manage a patient's systemic status during cataract surgery and that skilled nursing care is also available for the patient if needed.

#### Regulations

ASCRS maintains that infection prevention and control standards that apply to the ASC and HOPD sites of service would need to be established and applied to a non-facility setting. For surgeons who would operate on patients in non-facility settings, it is vital that there are safety standards, quality assurance/benchmarking requirements, and infection control regulations in place to ensure that patients are protected. Medicare accreditation and certification of ASCs and HOPDs have led cataract surgery to be highly successful with minimal complications because of the extensive safety measures in place. It is, therefore, necessary for infection control, sterility, and proper staffing to comply with state regulations and ASC standards. To guarantee appropriate infection prevention and control, regulation of office-based surgery at both federal and state levels, and the development of certification requirements for these non-facility surgical suites by CMS would need to be addressed.

#### **Possible Benefits of Office-Based Cataract Surgery**

One of the potential advantages that could be gained by establishing a non-facility payment for cataract surgery codes and providing an option for office-based cataract surgery would be greater flexibility in scheduling patients at the most appropriate location of service. This is especially true for surgeons residing in Certificate of Need (CON) states that are often restricted to where they can operate. There are currently 35 states, as well as Washington, D.C, operating a CON program, with some variations from state to state. As a result of restrictive CON laws, many of our members perform cataract surgeries in HOPD or multi-specialty ASCs. In these situations, there may be instances in which our members are in a position where they are unable to schedule their cataract surgeries in a timely manner. In states with CON laws, the ability to offer cataract surgery in an office setting would make scheduling procedures for patients and providers much more convenient.

Additionally, office-based surgery may be more convenient for patients, as they would visit one location to receive their surgery, as well as pre-and post-operative care, rather than visiting multiple sites. On the day of surgery, patients need a ride to their appointment. Additionally, it is common for patients to have blurry vision for a few days following their surgery, so it is highly recommended that

patients have a ride to their first post-operative appointment. Keeping all appointments in one location reduces the burden of traveling to multiple offices and may make it more convenient for the patient.

#### **Practice Expense (PE)**

If CMS moves forward with establishing a non-facility payment for the cataract surgery codes, CMS must go through the formal RUC process for establishing PE inputs. In the proposed rule, CMS notes that the nominator includes a list of practice expense items involved in furnishing these services in the non-facility setting to help consider establishing non-facility values for these codes. They include the possible number and types of clinical staff, their work time in minutes, and a list of various equipment and supplies typically needed to furnish the services. ASCRS cautions CMS with moving forward with PE values from an interested party with a vested financial interest in office-based cataract surgery and recommends that these values be established and analyzed through the formal RUC process.

In addition, there will be significant costs associated with providing cataract surgery in an in-office surgical suite that would need to be accounted for in determining an accurate non-facility payment rate. It would be imperative that CMS recognize costs for equipment, technology, anesthesia and nursing staff, certification requirements, labor, and other supplies. Other indirect expenses, such as the cost of construction and maintenance of an office-based surgical suite and increased overhead, would also need to be addressed. However, we reiterate that we have concerns with moving forward with establishing a non-facility payment for cataract surgery codes due to patient safety, the possibility of significant complications, and the lack of established standards for the construction, maintenance, sterility, and oversight of office-based surgery.

## II. 66174 and 66175 Dilation of Aqueous Outflow Canal

ASCRS strongly disagrees with CMS' decision in the CY 2022 MPFS to reject the RUC-recommend work values and move forward with a WRVU of 7.62 for CPT 66174 and a WRVU of 9.34 for CPT 66175. In the CY 2022 MPFS Final Rule, CMS finalized lower WRVU for CPT 66174 and CPT 66175 "using a reverse building block methodology" that does not accurately capture the intensity and complexities associated with performing these procedures. For example, CMS used CPT 15150, a skin graft procedure, to support the proposed values. However, this code does not correctly describe the intensity and complexity of the procedure. Other intraocular procedures have much greater intraservice work per unit of time (IWPUT) than the IWPUT of 0.0237 for CPT code 15150. As far as intensity goes, these procedures fall on the high end due to the complexity spectrum because it involves 360-degree microscopic cannulation of the Schlemm's canal, which is a structure of fewer than 20 microns in diameter in the typical glaucoma patient. Therefore, CPT 15150 is not appropriate to use as a comparator. Instead, we urge CMS to reconsider the RUC-recommended work value of 8.53 for CPT 66174 and 10.25 for CPT 66175.

We appreciate that CMS accepted 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 the placement of the stent in the canal. We agree with CMS and 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 further with additional reductions to CPT code 66174, we urge it to apply a phase-in period longer than two years for any further reductions. ASCRS is concerned by the significant rate reduction to CPT 66174 and requests CMS phase-in further rate reductions over the next three years to mitigate the adverse access effects it will have for beneficiaries and lessen disruption of clinical treatments for glaucoma. To reiterate, in the CY 2022 MPFS Final Rule, CMS did not accept the RUC recommendation and finalized a work value of 7.62 for CPT 66174, representing a substantial reduction (40.7%) from the CY 2021 WRVU of 12.85. While CMS planned to phase in the reductions over two years, ASCRS is concerned that the decrease to CPT 66174, and the significant physician reimbursement cuts scheduled to be implemented on January 1, 2023, may create access issues and disrupt patient treatments for glaucoma. Thus, we urge CMS to use its statuary authority to adopt a longer phase-in period to account for a total of four years, from CY 2022 to CY 2025, to ensure no disruptions in patient care.

# III. <u>Applying Increased E/M Values to Post-Operative Services in 10- and 90-day Global Surgery</u> Packages

ASCRS continues our strong opposition to CMS' continued failure to increase the value of post-operative E/M visits included in 10- and 90-day global surgery packages to correspond with the increased values CMS finalized for standalone E/M office visits that took effect January 1, 2021. This policy is broadly opposed, not just by ASCRS, but across all surgical specialties, the AMA, and members of Congress. As we have noted in joint letters from the surgical community, and from previous bipartisan letters from Congress, CMS must increase the value of the post-operative E/M services in global codes to correspond to increases in the standalone E/M codes that began on January 1, 2021, to be in compliance with the Medicare statute and to ensure the relativity of the fee schedule.

ASCRS is disappointed that CMS continues to speculate that the visits captured within the global surgical payment are not being performed, even though the global visits for cataract surgery, for example, have been recently verified in multiple analyses and were reaffirmed in the CY 2022 MPFS Final Rule. In CY 2019, cataract surgery was revalued through the AMA RUC process. ASCRS and the American Academy of Ophthalmology (AAO) surveyed a sample of our memberships and found that in addition to a slight time change, ophthalmologists were not providing 4 post-operative visits but rather 3 post-operative visits. This information was presented to the RUC, and the RUC, through their review process, made a revalued cataract code recommendation to CMS. CMS agreed and accepted the RUC recommended value, which included 3 post-operative visits (one level 2 visit and two level 3 visits). Furthermore, the RAND reports, which includes claims-based reporting of 99024 Post-operative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a post-operative period for a reason(s) related to the original procedure, support that ophthalmologists are indeed providing 3 post-operative visits following cataract surgery. The ophthalmology data for the recent office visit (99202-99215) survey reflect similar time and work as the primary care data, and RUC submitted overall data. It is, therefore, not appropriate to distort the relativity of the post-operative visits for cataract surgery. Furthermore, in the proposed rule, CMS notes that "some parties have challenged the methodology or conclusions of the RAND reports" and then goes on the say that it "believes the RAND has adequately responded to critiques of its methodologies and findings," thus suggesting it stands behind the validity of the RAND reports. Therefore, it is not appropriate for CMS to continue to choose not to provide equity to the cataract surgery codes when multiple data sources verify that the 3 post-operative visits are occurring during the global period.

In fact, CMS is ignoring the requirement by the Medicare statute to reimburse all physicians the same amount for the same work regardless of specialty. By increasing the value of just the standalone E/M codes, and not applying the increase to the global codes, CMS is disrupting the relativity of the fee schedule. Further, each time E/M codes have been revalued since their inception in 1992, the post-operative E/M services in the global surgical codes have also increased. CMS should be consistent with its prior policy and follow the recommendation of the RUC to increase the values.

ASCRS maintains that the best way to determine the value of a typical post-operative surgical visit is to rely on the AMA RUC and the RAW. In the last ten years (2012-2022), the RUC has reviewed 270 10- and 90-day global surgical codes where the number of post-operative visits was verified. In fact, all high-volume services and the top allowed charges for 10- and 90-day services have been RUC reviewed and finalized by CMS in the last 10 years. The RAND studies and the evaluation of claims-reporting data for cataract surgery verify that the RUC recommendations are a sound and accurate way to determine the frequency of the global visits. If CMS does not believe post-operative E/M services in the global period are occurring, we recommend CMS send them to the RUC for reevaluation. At a minimum, for all 10-and 90-day global surgical codes that have been recently revalued and confirmed by CMS, like the cataract surgical codes, the agency should adjust the E/M payment immediately to reflect the updated payment increases applied to the standalone E/M codes that were implemented on January 1, 2021.

To reiterate our reasons why CMS must increase the value of post-operative E/M services in 10- and 90-day global codes:

- Failing to increase the value of post-operative E/M services is a direct threat to the overall relativity of the physician fee schedule. As mandated by Congress, physician services are valued through the resource-based relative value scale (RBRVS) that takes into account the relative work, practice expense, and malpractice insurance costs required to furnish a particular service. Since the inception of the fee schedule, post-operative E/M visits have been valued equally to standalone E/M office visits—and have been increased when E/M codes were previously revalued. To abandon this long-standing policy of valuing post-operative and standalone E/M visits for CY 2023 continues to disrupt the relativity of the fee schedule. To maintain the relativity of the fee schedule and ensure that services with similar work, practice expense, and malpractice costs are valued equally for CY 2023, CMS must increase the value of post-operative E/M visits included in global surgery bundles to be equal to the value of standalone E/M services.
- CMS' policy violates the Medicare statute requiring Medicare to reimburse physicians equally
  for the same service, regardless of specialty. Since 10- and 90-day global services are
  overwhelmingly provided by surgical specialties and not primary care physicians, failing to

increase the value of post-operative E/M visits creates an illegal specialty differential. The work, practice expense, and malpractice costs of post-operative visits are similar to those components of standalone E/M services, and therefore, they should be valued at the same level. **To ensure** CMS does not run afoul of the current statute barring specialty differential payments, the agency should increase the value of post-operative E/M visits included in global surgery bundles along with standalone E/M services in CY 2023.

• The AMA RUC continues to recommend that post-operative E/M codes in global services be increased to correspond with the increase in the standalone E/M codes. CMS adopted the RUC's recommended values for standalone office visit codes following an extensive review and revaluation. CMS has made note of the extensive energy devoted to updating the codes and the robust survey process. As we have previously noted, ASCRS and other surgical specialties participated in the survey of E/M codes, and the responses of our members detailing the work related to furnishing these services are reflected in the final values. Most importantly, CMS should follow the precedent set in 1997, 2007, and 2011 (in accordance with the Medicare statute) when E/M codes were previously revalued and increase the value of the post-operative visits included in the global packages as it did in those three previous times.

Furthermore, the RUC is the most appropriate venue for revaluing global surgical codes. As indicated above, CMS implemented the RUC-recommended value for cataract surgery (66984) in CY 2020 and confirmed the value again in the CY 2022 MPFS Final Rule. For that code, RUC survey data indicated that 3 post-operative visits are typically performed and represent similar work, practice expense, and malpractice costs as furnishing a standalone E/M visit. However, by failing to increase the value of post-operative visits included in global codes, CMS is arbitrarily devaluing not just E/M visits after cataract surgery, but all services without applying the same rigorous analysis employed by the RUC that determines the relative value of each individual service in the physician fee schedule. If CMS believes that certain codes include post-operative visits that are not being performed, it should refer those specific codes to the RUC as potentially misvalued and requiring review, rather than applying a broad policy to devalue all post-operative E/M services.

## IV. <u>Telemedicine</u>

ASCRS supports CMS' proposed expansion of the Medicare Telehealth Services list on a permanent basis, CMS' proposal to further expand the Medicare telehealth services list on temporary (Category 3) basis, and CMS' proposal that all PHE allowances for telehealth last for 151 days after the PHE ends. The flexibilities for telehealth services provided for by CMS during the PHE have enabled ophthalmic practices to provide ongoing essential medical care and treatment throughout the PHE. Using its authorities under the PHE and those granted by congressional action, CMS was able to assure that Medicare beneficiaries could receive care and treatment from their homes using a variety of technology, including audio-only telephones. Some of our most impactful telehealth visits (impactful to patients and to the entire health system) are for new patients. As we previously shared, our members have seen countless examples of urgent triage visits, second opinion consults, and physician/physician consults, which enabled timely care for serious conditions. Conversely, these visits minimize unnecessary emergency department visits and travel for subspecialty care. We thank CMS for acknowledging Medicare beneficiaries' need for additional

access to care during the PHE.

ASCRS urges CMS to continue to allow for audio-only E/M services (99441-99443) by keeping them on the Medicare Telehealth Services List after the end of the PHE and the 151-day post-PHE extension period. The availability of audio-only services has had a profound impact on Medicare beneficiaries who lack the financial resources and local broadband infrastructure to utilize more traditional telehealth modalities. In addition, a large segment of the cataract patient population is older, less comfortable, and less familiar with using technology that enables video communications compared to audio communications. It is also likely that many beneficiaries may not have access to video communication platforms. By removing audio-only services, CMS would be doing a great disservice to the Medicare beneficiary population. Therefore, we urge CMS to continue allowing audio-only services to remain available.

We would like to highlight that many of our members invested in virtual platforms during the PHE to continue providing patient care due to restrictions around in-office visits. Many terms need to be met to offer telehealth services, including properly educating staff, understanding supervision requirements, as well as state scope of practice, licensing, and any applicable state or local laws. For these reasons, we urge CMS to recognize the significant education and financial investments that practices have made to expand access to telehealth services by providing additional guidance that clearly defines supervision requirements, as well as state scope of practice and licensing, and any applicable state or local laws, to help better ensure the quality of care for telehealth services. Furthermore, due to the substantial time and monetary investments that have been made by practices to implement telemedicine platforms, in addition to the issue of continued access for Medicare beneficiaries, we encourage CMS to consider extending audio-only coverage for telehealth services beyond the PHE to ensure our members can continue to maximize the benefits of telehealth and enhance patient access to care.

V. <u>Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts</u>

ASCRS has concerns with CMS' proposal to use a new modifier, JZ, to indicate that no amount from a single-use vial or single-use package was discarded, as it creates an unnecessary burden for ophthalmologists. We also urge CMS to exempt ophthalmic drugs by using its statutory authority to raise the wastage threshold applicable to the rebate requirement for drugs with volumes less than 1 mL per vial.

ASCRS maintains that the proposed JZ modifier is unnecessary and will place an additional administrative burden on ophthalmic practices that are already strained with keeping up with day-to-day demands. CMS has required the JW modifier since 2017 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. According to CMS, providers do not always apply the JW modifier when portions of a drug are discarded. Based on this concern, CMS is proposing the implementation of a new modifier, JZ, where physicians will be required to report it every time the full amount of a drug is administered "to attest" that no drug was wasted. However, this is simply an additional administrative burden for ophthalmic practices. Most single-use vials and packages in ophthalmology are used entirely

and are not adjusted for patient weight, so requiring the JZ modifier would result in an additional administrative burden for practices. **We encourage CMS to consider ways to use claims data already being collected to verify drug waste.** 

Moreover, the proposal's intent seems to be misdirected when it comes to exceptionally small vials and equally small fills, like those used in ophthalmology. Small amounts of drug product injected into the eye are often in vials containing 1mL or under of drug. While not every microliter of the drug may be extracted from a vial for injection, there must be sufficient volume in order to properly mix in the vial and draw with a syringe. What remains in the vial would not seem to meet the definition of "wastage" and would create a substantial amount of extra work for physicians and practice staff to attempt to reconcile any tiny amounts of product remaining in these small vials. Therefore, we urge CMS to exempt ophthalmic drugs by using its statutory authority to raise the wastage threshold to 100% for drugs with volumes less than 1 mL per vial.

## VI. <u>MEI</u>

ASCRS supports CMS' recognition that the data currently used for the MEI is outdated and needs to be revised, but we believe the AMA should complete its data collection project for practice costs before CMS considers using other outdated data. CMS proposes to update the MEI weights using 2017 data from the United States Census Bureau's Service Annual Survey (SAS). There are several limitations associated with using SAS data to update the MEI cost weights, including CMS' estimate that grossly underestimates compensation for physician practice owners. Most importantly, the proposal would significantly redistribute Medicare dollars from "physician work" to "practice expense," diminishing physicians' specific contribution to the health care system.

A significant effort is underway by the AMA to collect practice cost data from physician practices. Data collected by the AMA has been a consistent source of information about physicians' earnings and practice costs for the MEI. The MEI plays a vital role in measuring practice cost inflation (and will likely play a similar role in the future). Thus we urge CMS to pause considering other sources of cost data for use in the MEI until the AMA has completed its efforts.

#### **QUALITY PAYMENT PROGRAM**

ASCRS thanks CMS for minimizing the number of substantial proposed changes to MIPS, particularly as we continue to deal with the repercussions of the COVID-19 public health emergency.

# I. <u>MIPS Value Pathways (MVPs)</u>

#### **MVPs Must Remain Voluntary**

In the CY 2022 MPFS proposed rule, CMS indicated an eventual requirement that all physicians participate in MVPs and their intention to sunset traditional MIPS by the end of the 2027 performance and data submission periods. In this proposed rule, on page 173 of the prepublication, CMS reinforces that MVPs

may become mandatory in the future. ASCRS strongly urges CMS to make MVPs a voluntary participation option when implemented.

- As we noted in our comments on the CY 2021 and 2022 MPFS proposed and final rules, our opposition to the current framework outlined by CMS is that MVPs continue to be chiefly based on CMS' intent to eventually make them mandatory and phase-out MIPS. We appreciate that CMS continues to seek feedback from stakeholders before making formal proposals or implementing the new framework. However, CMS also intends to build a robust inventory of MVPs and expects that eventually all MIPS eligible clinicians would be required to participate in MIPS either through an MVP or an APM Performance Pathway (APP), while no longer offering traditional MIPS. Given that the goal of MIPS is to provide a more flexible approach to quality reporting, clinicians participating in the program must continue to have options in how they participate in the program. It is critical that MVPs remain voluntary and that physicians maintain the ability to participate in either an MVP or remain in the traditional MIPS pathway, so they have continued flexibility to choose the measures that are most appropriate for their practice and patient population.
- Physicians are best suited to select the measures that are most meaningful to their practices and patients. While ophthalmology is solely focused on the diseases of the eye, there are several different subspecialties, and not all ophthalmologists of a particular specialty focus on the same population of patients. For example, the retina subspecialty focuses specifically on diseases at the back of the eye, neuro-ophthalmologists focus on visual problems related to the nervous system (not the eyes), and cataract and refractive surgeons focus on the front of the eye.

Given that diversity, it would be difficult to identify a limited set of measures and activities that would be useful to all ophthalmologists. This was quite evident when CMS initially developed a draft MVP for ophthalmology. As was discussed in our meetings with CMS regarding the draft proposal, not all ophthalmic specialties would have been able to participate.

In the recent update CMS has circulated, an MVP encompassing all of ophthalmology would severely limit the ability of ophthalmologists to perform well under MIPS. In the new draft Comprehensive Ocular Care MVP, 12 of the 18 available quality measures are either not benchmarked or topped-out. In addition, not all ophthalmic subspecialties have measures available in the draft MVP. The only cost episode measure available to ophthalmologists is the "Routine Cataract Removal with IOL Implantation."

We have encouraged the development of MVPs around conditions and procedures. In fact, the ophthalmic community recognized this fact several years ago, and has been successful in developing a focused set of measures—many of which are outcome measures—that reflect our members' practices and patient population. CMS should allow specialty societies, if they so desire, to work with CMS on a particular clinical condition or procedure, but these efforts should be clinician led. However, we continue to urge CMS to allow physicians to select and report on the most clinically relevant measures and designate MVPs as voluntary participation options.

It is crucial that MVPs be voluntary to preserve physicians' ability to report on the measures they believe are the most relevant to their practice and patients. Ophthalmology has developed a comprehensive set of meaningful measures, including several outcome measures, that give ophthalmologists options for selecting those that are the most clinically relevant.

#### **Eliminate Flawed Population Health Measures**

- CMS should rethink its continued plan to include flawed population health administrative claims measures as a foundation in MVPs, and in the MIPS program at-large. As we have noted in our comments on previous rules and other requests for information, population health measures, such as the all-cause hospital readmission currently used in MIPS for large practices, are primary care-based and nearly impossible for specialists, such as ophthalmologists, to influence or even predict what patients will be attributed. Ophthalmologists focus entirely on one organ or system. Ophthalmologists only treat diseases related to the eye and do not manage their patients' overall health care. Population-health measures are focused on managing the outcomes of a group of patients, usually through preventative care and care coordination, which is not possible for ocular disease. Using these measures to determine the quality of ophthalmic care is entirely inappropriate. Ophthalmologists should be excluded from these measures, and population health measures should not be included in any ophthalmic MVPs.
- Ophthalmologists' experience to date with population health measures has been meaningless, and CMS has acknowledged this by excluding them and other specialists from the total per capita cost measure in the Cost category. Oftentimes, as we saw under the legacy Value-Based Payment Modifier program, ophthalmologists were attributed measures related to cardiac, urinary, and pulmonary care simply because they happened to bill E/M codes. Our members had no way to predict what patients they would be attributed and could take no action to improve their scores. As referenced above, CMS has recognized that ophthalmologists and other specialists were being attributed the cost of care they did not provide and excluded them from the total per capita cost measure. Given that ophthalmologists and other specialists are excluded from that measure, it is inappropriate to consider subjecting them to other claims-based population health measures. While we understand that CMS may view claims-based measures as a strategy to reduce administrative burden for physicians, ophthalmologists and other specialists view being scored—and potentially penalized—on these meaningless measures as a far greater burden than reporting on clinically relevant measures, such as cataract surgery outcome measures.

#### **Reduce Reporting Burden of Patient-Reported Outcome Measures**

• ASCRS continues to recommend CMS eliminate the burden associated with collecting data for patient-reported outcome measures proposed to be included in MVPs, and the MIPS program in general. We have long supported the use of appropriate patient-reported outcome measures and participated in the development of several related to cataract surgery. These measures are valuable following cataract surgery since they can demonstrate that patients are experiencing improved quality of life. However, they are currently not feasible to use in MIPS because the data completeness threshold is so high, and it is impossible to administer the surveys to patients undergoing this high-volume procedure. The current patient-reported outcome measures, QPP303 and QPP304, are registry-only and will continue to require a 70% data completeness

threshold in 2022 (75% in 2024-2025) of all patients undergoing this high-volume procedure. The AAO's IRIS Registry does not currently offer these measures because it does not have the resources to collect and score the volume of surveys it would receive in conjunction with these measures. In previous years, we have recommended that CMS modify the data completeness threshold for patient-reported measures to require just a representative sample or reinstate the measures group options available under the Physician Quality Reporting System (PQRS) that required these and the other cataract outcome measures only be reported on 20 patients. We urge CMS to reduce the burden associated with patient-reported outcome measures if included in MVPs and MIPS in general.

## **Streamline Scoring Methodology**

Rather than force physicians to report on mandatory MVPs that may not reflect their clinical practice and maintain the complicated separate scoring methodologies for each category, we continue to recommend CMS work to streamline the existing MIPS program. Along with others in the medical community, ASCRS has proposed a voluntary and flexible system that would award physicians credit across categories for clinically relevant measures and activities. In comments on previous years' rules, we recommended that CMS take steps to make the scoring more predictable, such as eliminating different scoring methodologies for each category and aligning the points available with the weight of the category. We appreciate that CMS took some steps toward this in 2021 by eliminating the confusing base and performance score of the PI category. In addition, we encouraged CMS to identify areas where physicians could earn multicategory credit. For example, as we will discuss in more detail later in this letter, we continue to recommend physicians using a Qualified Clinical Data Registry (QCDR) integrated with their EHR to collect Quality data also be awarded full credit in the Promoting Interoperability PI category, since they are using the CEHRT in a more relevant way than the measures in that category. We continue to believe that these modifications would reduce confusion physicians often experience trying to adhere to the disparate requirements in each of the categories and make the program more meaningful for all physicians.

Again, we maintain our opposition to mandatory MVPs and urge CMS to preserve physician choice.

Finally, although MVPs are meant to be a cohesive, integrated reporting pathway, clinicians will still be subjected to different scoring in each category and would not receive credit in multiple categories for high-value measures or activities. As we have in previous comments, we urge CMS to work with the medical community to streamline the program by simplifying scoring and allowing for cross-category credit as a means of truly reducing burden.

#### **Develop Condition-Based/Procedure MVPs**

In the past, CMS has expressed concern that the number of MVPs desired is too high. In ophthalmology, we are highly subspecialized and cannot reliably or meaningfully be scored in a specialty-wide MVP. Therefore, we urge CMS to consider the adoption of more subspecialty and condition-based MVPs.

# **Subgroup Scoring Proposals**

#### Quality Outcomes-Based Administrative Claims Measure Scoring

CMS is proposing that, for each selected outcomes-based administrative claims measure in an MVP, subgroups would be assigned the affiliated group's score, if available. If a group score is not available, CMS proposes that each of these measures will be assigned a zero score. **ASCRS strongly opposes this proposal.** Since subgroups elect their administrative claims measure with the intent that it be specific to the population their specialty treats, it is inappropriate to assign the group score by default. Subgroups should only be assigned the group score if a subgroup score cannot be calculated.

Likewise, it is inappropriate to assign a score of 0/10 on a measure simply because neither the group nor the subgroup can be reliably evaluated on the measure given available data. In this case, the measure should, instead, be suppressed for that subgroup. This would mirror the Cost measure subgroup scoring proposal.

#### Cost Measure Scores

CMS is proposing that subgroups would be assigned the affiliated group's cost score, if available for the Cost performance category in an MVP. If a group score is not available, CMS proposes that each of these measures be excluded from the subgroup's final score. **ASCRS supports this proposal.** 

## • Population Health Measure Scores

CMS is proposing that, for each selected population health measure in an MVP, subgroups would be assigned the affiliated group's score, if available. If a group score is not available, each of these measures would be excluded from the subgroup's final score. **ASCRS opposes the proposal to assign the group score to the subgroup by default.** Since subgroups elect their population health measure with the intent that it be specific to the population their specialty treats, it is inappropriate to assign the group score by default. Subgroups should only be assigned the group score if a subgroup score cannot be calculated. **We support the proposal that, if a group score is not available, each population health measure be excluded from the subgroup's final score.** 

# II. Quality Category

# Timeline to Switch to 2015 Cures Update CEHRT

ASCRS is concerned with the progression toward viable adherence with CMS' previously finalized policy requiring providers to transition to 2015 Cures Update CEHRT by the beginning of the 2023 MIPS PI performance period of the clinician's or group's choice during the 2023 MIPS performance year. As of August 1, 2022, only a few major vendors have received full Cures Update certification.

We request clarification on the impact that this requirement will have on clinicians and groups reporting electronic clinical quality measures (eCQMs):

- Will those EHR-integrated with a certified QCDR be able to continue reporting eCQMs even if their EHR is unable to get Cures Update certified?
- Will clinicians and groups be able to report eCQMs for MIPS via their EHR if the EHR is unable to get Cures Update certified by the beginning of 2023? What if the EHR is unable to get Cures Update certified by the end of 2023?
- If any of the above circumstances occur, will CMS provide Quality category Extreme and Uncontrollable Circumstances (EUC) hardships to those clinicians and groups for EHR decertification?

**ASCRS strongly urges CMS to provide sufficient time for clinicians to upgrade and implement Cures Update CEHRT.** The Office of the National Coordinator for Health Information Technology (ONC) mandate requires EHRs to be updated by December 31, 2022. It is unreasonable to expect clinicians and practices to be able to implement the Cures Update or switch to a new EHR that is able to obtain Cures Update certification in such a short time frame, and manually submitting quality measures, especially if a practice was planning to submit eCQMs, presents a significant burden.

# **Data Completeness Threshold**

ASCRS appreciates and supports the CMS proposal to continue the data completeness threshold at 70% for the 2023 performance period, but we do not support CMS' proposal to increase the threshold to 75% for performance years 2024 and 2025, and we urge CMS to reconsider.

Increased reporting requirements directly intensifies administrative burden for physicians and does not align with the Patients Over Paperwork Initiative. In fact, some small and rural physicians have indicated that further increases may make submitting data to MIPS too burdensome and may stop submitting data. This problem is even more pronounced for patient-reported outcome (PRO) measures, as it is difficult to obtain sufficient patient responses under current thresholds. In acknowledgment of the widespread difficulty in obtaining PRO responses from patients, we recommend CMS consider setting lower data completeness thresholds for patient-reported outcome measures.

## **Support for Maintaining 3-Point Floor for Small Practices**

ASCRS supports CMS' decision to maintain the 3-point floor for quality scoring for small physician practices.

## **Support for Maintaining 6-Point Bonus for Small Practices**

ASCRS supports CMS' decision to maintain the 6-point quality for small physician practices.

# <u>Proposed Modifications to Previously Finalized Specialty Measures Sets</u>

**ASCRS** has significant concerns with the proposal to add "Optometry" to the title of the Ophthalmology specialty set. This "regulatory" combination conflates the difference between the two specialties in regard to education, clinical knowledge, and licensure, as it relates to the treatment of patients. Based on our experience with licensure issues at the state level, adding optometry to the ophthalmology measure set would have serious implications for inappropriate expansion of the scope of procedures and increase

patient safety concerns. Therefore, we urge CMS not to move forward with adding Optometry to the Ophthalmology specialty set.

#### **Measures Proposed for Removal**

• QPP 117: Diabetes Eye Exam (Claims)

ASCRS strongly opposes the proposed removal of QPP117: Diabetes Eye Exam for the claims collection type. Not only is this an important measure, but ophthalmologists reporting via claims already have very few measures germane to their practice on which to report. Removing this measure will disproportionately and negatively impact small and rural ophthalmic practices, which are less likely to be able to afford CEHRT adoption. We strongly encourage CMS to maintain the availability of this measure via the claims collection type to continue to allow meaningful measurement of ophthalmologists and ophthalmic subspecialists in small and rural practices.

QPP 110: Preventive Care and Screening: Influenza Immunization (All Collection Types)

ASCRS opposes the proposed removal of QPP110: Preventive Care and Screening: Influenza Immunization and combining it with other immunization measurements in a new Adult Immunization Status measure. Creating ever more complex, multi-factor quality measures is increasing the burden on physicians. For example, the new Pneumonia Immunization measure specification (requiring a determination of whether the vaccine was given on or after the patients 60<sup>th</sup> birthday) has created significant unforeseen difficulties in reporting. We believe that accurate and actionable vaccine information is important, particularly in light of current infectious disease public health emergencies. Keeping these measures separate will facilitate analysis of immunization rates for each vaccine and identification of priority areas. Combining these measures will create additional burden and, as we have seen with the Pneumonia vaccination measure, decrease reporting rates on these important and timely measures.

# **Topped-Out Measures**

• Topped-Out Measure Lifecycle for Truncated and Suppressed Measures

We appreciate and support CMS' clarification on the topped-out measure lifecycle for these measures.

Topped-Out Measure Scoring Caps and Removal of Topped-Out Measures

As we have stated previously in these comments, ASCRS continues to oppose CMS' topped-out measure methodology and recommend that CMS continue to award credit to physicians who maintain high quality, particularly on outcome measures. Under the topped-out measure methodology, CMS determines what measures are available by an arbitrary quantitative level that does not consider the clinical relevance of the measure or the volume of Medicare services it impacts. For example, while cataract surgery is a highly successful surgery, it requires intense training and physical skill to perform. While rare, complications could include total vision loss. Coupled with the high volume of cataract surgery

performed on Medicare beneficiaries, CMS risks wide gaps in the number of Medicare services that are subject to quality measurement if it removes measures related to cataract surgery.

In addition, it is critical to continue measuring the outcome of highly successful surgeries like cataract surgery to ensure surgeons are continuing to achieve good outcomes. Therefore, CMS should maintain cataract surgery outcome measures in the program, refrain from removing any further measures, and continue to award full credit to surgeons who maintain high quality. The ophthalmic community has worked to develop a robust set of outcome measures related to cataract surgery, and surgeons continue to provide high-quality care to their patients, as evidenced in their superior performance on these measures. We continue to urge CMS to maintain clinically relevant measures related to cataract surgery in the MIPS program and to award full credit to physicians who maintain high quality.

Due to the ongoing impacts of the COVID-19 pandemic, we also request that CMS suspend the topped-out measure scoring caps for 2023. As we have already indicated, we oppose the elimination of topped-out measures, as well as capped scoring. Current determinations of topped-out performance may not be accurate due to the ever-changing program requirements from year to year. All these concerns are exacerbated considering the continuing PHE.

## Social Drivers of Health Request for Information (RFI)

We agree that Social Drivers of Health (SDOH) must be considered within all areas of health policy, and ASCRS believes that MIPS quality measures are not the most effective way to collect data on health equity. Our concern is that the data collected through a quality measure would be limited in usability due to data collection standards set by HHS, creating a fundamental incompatibility with data collected by other CMS programs. We also recommend that SDOH measures not be required until CMS is able to produce and provide clinicians with up-to-date, community- and need-specific resources to give to patients who screen positive.

Additionally, many health equity needs are complex in nature, and fall outside the scope of medical practitioners to address. Requiring physicians, who are already overstrained and overburdened, to take on the labor of a social worker is unreasonable. Moreover, without providing clinicians with easy-to-use, centralized resources to give to patients who screen positive, CMS would be contributing to a degradation of the provider-patient relationship, as the identified needs of patients would not be able to be adequately addressed.

We recommend instead, that if health equity impacts are to be increasingly incentivized within the MIPS framework, that efforts concentrate on Improvement Activities that help support these aims, under the "Achieving Health Equity" subcategory.

#### III. Cost Category

We remain concerned that the Cost category has not yielded predictable results based on practice patterns and best practices and encourage CMS to consider the stakeholder feedback received in the review of Wave 1 measures.

## **Cataract Surgery Episode-Based Cost Measure**

ASCRS remains concerned that the cataract surgery episode-based cost measure disincentivizes the use of drugs that are separately paid to promote a policy priority, such as the pass-through payment policy and the non-opioid pain management exclusion to packaging drugs used during surgical procedures. Therefore, we ask CMS to consider suspending the use of this measure in MIPS as it undertakes a full review of the measure and its specifications.

# High-Level Summary of our Comments from the Wave 1 Cataract Cost Measure Reevaluation:

- **Trigger Code:** 66984 should remain the only trigger for the cataract episode-based cost measure as it is the only routine cataract code and comprises the vast majority of billed cataract surgeries.
  - Other cataract codes are for complex cataracts that are likely to be more expensive due to factors outside of clinician control. Complex cataract may require additional supplies and increases the likelihood of potential complications.
- **Exclusions:** Maintain all current exclusions. It is vital to remove the variable of comorbid ocular conditions in order to ensure reliable measurement. This will allow for more meaningful comparisons and not penalize clinicians who treat patients with comorbidities.
- Pass-through drugs and drugs on special payment status: No pass-through drugs nor drugs on special payment status (e.g., non-opioid pain management drugs excluded from payment packaging) should be included in cost measure calculations. The extra cost will disincentivize surgeons from using the drugs and negatively impact the utilization data CMS collects on passthrough drugs during the pass-through period.
- Part D Drugs: Part D drug costs should not be included in cost measures. To our knowledge, CMS does not have the capability to standardize all Part D drug cost variations. Physicians have no control over the negotiations between drug manufacturers, pharmacy benefit managers (PBMs), and insurers that will ultimately determine Part D prescription drug costs.

# IV. <u>Promoting Interoperability Category</u>

## <u>Timeline to Switch to 2015 Cures Update CEHRT</u>

ASCRS is concerned with the progression toward viable adherence with CMS' previously finalized policy requiring providers to transition to 2015 CEHRT by the beginning of the 2023 MIPS PI performance period of the clinician's or group's choice during the 2023 MIPS performance year. This policy was finalized to align with the ONC's December 31, 2022, deadline for certified EHR vendors to make 2015 Cures Update available to their customers.

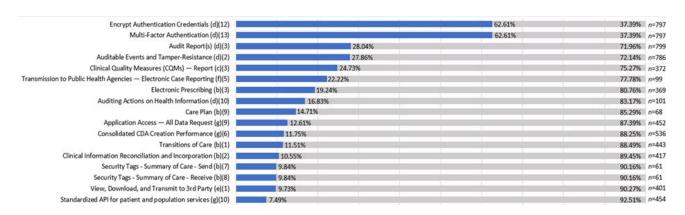
We strongly urge CMS to monitor the progress of EHRs receiving the Cures Update certification. As of August 1, 2022, only a few major vendors have received full Cures Update certification. This fact was

shown starkly in the March 3 *HealthITBuzz* blog post<sup>1</sup> written by ONC officials Jeff Smith, Tony Myers, and Papia Paul:

"There are several other important Cures Update certification criteria where considerable progress will need to occur throughout the year to meet the December 31, 2022, deadline, including the new standardized FHIR application programming interface (API) for patient and population services,"

A more recent ONC blog post also contained the chart below showing the percent of products currently certified to each of the Cures Update criteria that are, at present, required by December 31, 2022.<sup>2</sup>

# Progress of Certification to the 2015 Edition Cures Update Criteria Required to be Available by December 31, 2022 (as of August 2022)



Substantial progress needs to be made in the next five months for all clinicians to have access to the Cures Update from their current vendor. Adopting, upgrading, or switching EHRs is expensive and takes a long time to implement. Before the first day of use of a new EHR at a practice (at the "go-live" moment), there is generally a year of preparation. This includes preparing old records for transition, training staff, and other data-merging activities. Rushing this process can lead to missing records, missing diagnosis codes, improper access designations, inability to transmit electronic prescriptions, and other meaningful issues that prevent or significantly harm patient care. When these concerns are coupled with the widely documented staff shortages across the health care sector because of the workforce decimated by the pandemic, it is imperative that providers be given adequate time to install these new updates before being required to use the updated software for MIPS.

Given the low percentage of vendors certified to most of the criteria, including only 7.49% certified to the API criterion, we ask CMS to ensure that clinicians using an EHR vendor that does not meet the deadline for the Cures Update have access to the PI decertification hardship exception for the 2023 reporting year. Although ONC states that the vendors which have (g)(10) API certification represent 77%

 $<sup>^{1}\,\</sup>underline{\text{https://www.healthit.gov/buzz-blog/healthit-certification/an-upcoming-milestone-in-our-interoperability-journey}}$ 

<sup>&</sup>lt;sup>2</sup> https://www.healthit.gov/buzz-blog/healthit-certification/on-the-road-to-cures-update-certified-api-tech

of ambulatory clinicians, it is clear from other statements and from conversations with our members that this 77% represents practices that can afford vendors with a larger market share and that these practices are often affiliated with a hospital or health system.

#### **General Comments on Category Scoring**

As CMS looks toward developing policies reducing the burden of the MIPS program, we continue to recommend that the "all-or-nothing" methodology for this category be removed. We also urge CMS to consider a more diverse set of measures that offer more relevant options for specialists rather than measures that focus on the CEHRT functionalities instead of patient care. We also urge CMS to continue to limit regulatory requirements in this category if physicians share data among themselves and with their patients. In addition, we continue to recommend that physicians who use QCDRs that integrate with their EHR be awarded full credit in this category.

- CMS should remove the "all-or-nothing" scoring of this category. Congress intended for MIPS to award clinicians for attempting to participate in quality reporting programs, rather than penalize them for not achieving 100% success. In the other categories of MIPS, clinicians can earn some credit—and potentially minimize negative payment adjustments—by reporting what is achievable. Therefore, it seems inconsistent that to score any points in the PI category, clinicians must report on all required measures, regardless of whether they are relevant to their practice. We appreciate that CMS is continuing to offer its small practice hardship exemption, which is valuable to many small ophthalmic practices that may struggle to afford or implement CEHRT in their practices. However, as we have stated previously, there is no incentive for practices to try and implement CEHRT into their practices if they are unsure that they can be completely successful in the category. Awarding partial credit or allowing clinicians to attest to having certain functionality would reduce the burden associated with this category and may encourage more clinicians to participate. We continue to recommend CMS modify this category and remove the "all-or-nothing" scoring and one size-fits all approach.
- We also continue to recommend that CMS award full credit in the PI category to any physician or group who participates in end-to-end electronic reporting through a QCDR. Ophthalmologists have access to the IRIS Registry, a QCDR that integrates seamlessly with most EHR systems and provides them with full reporting capabilities for MIPS. The use of the QCDR is a clinically relevant tool to provide a full picture of the physician's performance. PI measures are process related and generally primary care based. They do not provide useful information to specialists, such as ophthalmologists. Physicians using a QCDR are participating at a higher, and more meaningful, level in MIPS and should be given full credit in the PI category, so they can focus on clinically relevant measures.
- We believe this recommendation aligns with our call to continue to streamline and simplify the
  MIPS program and provide multi-category credit. A significant percentage of cataract surgeons
  and multi-specialty ophthalmology practices have already integrated their EHR systems with the
  IRIS registry. This allows them to make full use of their EHRs to keep track of surgical outcomes
  and ensure that patients with chronic disease are receiving regular care. We believe this tool
  meets the ideals of the MIPS programs as envisioned by Congress to take a holistic approach to

quality reporting, rather than the rigid framework that CMS is proposing for the MVPs. We continue to encourage CMS to award full credit in the PI category for clinicians who have an EHR integrated with a QCDR and to identify additional opportunities for cross-category credit.

## **Maintenance of Automatic Small Practice PI Hardship**

ASCRS supports CMS' decision to maintain the automatic small practice PI hardship exception. This automatic hardship exception and reweighting has helped to alleviate some of the burden experienced by small practices reporting MIPS.

<u>APM PI Reporting:</u> *Allowing APM Entities to Report PI at the APM Entity Level* **ASCRS supports this proposal.** We believe it will streamline reporting for clinicians in APMs.

## Requiring the PDMP Measure and Changes to the PDMP Measure

ASCRS agrees that the opioid epidemic is a problem that needs to be addressed and that reviewing the PDMP is a good step in that direction. However, we are concerned that this measure, as proposed, is confusing and will inappropriately disadvantage specialists who do not prescribe opiates or other controlled medications, which ophthalmologists typically don't do.

## Expansion of the Measure to Include Schedule III and IV Drugs

The wording of the proposed expansion of this measure is confusing and we request clarification. If finalized, will the Schedule III and IV drugs be limited to opiates? Will the Schedule II drugs covered by this measure be expanded to include non-opiate medications?

#### Low-Volume Exclusion

Ophthalmologists rarely, if ever, prescribe opioid medications. Many have even relinquished their DEA certification. This measure requires an exclusion for low-volume prescribers that is specific to opiates and, if the proposal to expand the measure is finalized, Schedule III and IV drugs. As proposed, the low-volume exclusion language includes all permissible prescriptions. The CMS definition of permissible prescriptions is the following:

"All drugs meeting the current definition of a prescription as the authorization by a clinician to dispense a drug that would not be dispensed without such authorization and may include electronic prescriptions of controlled substances where creation of an electronic prescription for the medication is feasible using CEHRT and where allowable by state and local law."

Providing a low-volume exclusion specific to the medications covered under the finalized measure will allow clinicians who are already doing their part to mitigate the opioid epidemic to avoid being penalized on these measures.

Public Health and Clinical Data Exchange Objective: Limiting Active Engagement Option 1 to One Year

**ASCRS strongly opposes the proposal to limit the amount of time clinicians can be in Pre-production and Validation.** The move from Pre-production and Validation to Validated Data Production is not only clinician-dependent, but also clinical data registry (CDR) – or public health agency (PHA) – dependent, as the CDR or agency must qualify the data. It can take months, or longer, of work for a clinician to get their data qualified for a single registry, let alone multiple required registries. We have heard from members that getting to Validated Data Production can take well over a year and is widely variable based on the clinician's state and locality.

Given these issues, clinicians need additional time to move from Pre-production and Validation to Validated Data Production or there must be an exclusion for clinicians unable to comply with this short timeline with the resources they have available or due to the PHA's or CDR's inability to meet the timeline CMS proposes.

## **Provider-to-Patient Exchange RFI**

ASCRS is extremely concerned with CMS' discussion of adding a patient access measure to their health information. The previous measure that did this (View, Download, and Transmit) was a deeply problematic measure, particularly for ophthalmology. Not only is it inappropriate to score clinicians on a metric over which they have no control, in ophthalmology many of our patients are older and suffer from low vision, making reading on screens difficult or even painful. We have even heard from several practices that, when this measure was in place, they had to hire interns or additional staff to sit in the waiting room with patients to help them sign into the portal and view their information, as many patients did not have access to a computer or smart phone at home. One-time access in the waiting room is not the intended purpose of this measure, but it was the only avenue some practices had to avoid being penalized.

Reinstating any form of a measure that requires patients to actively access their information creates burden on both practices and patients. We strongly urge CMS not to take this step backward.

#### <u>Trusted Exchange Framework and Common Agreement (TEFCA) RFI</u>

ASCRS strongly recommends CMS not require TEFCA participation in any future year. Currently, TEFCA is still in its infancy, with the Common Agreement and Qualified Technical Framework only released earlier this year. Pushing adoption at this stage would be premature. We would, however, approve of providing easy-to-understand, multi-modality education to providers to allow them to analyze workflows, costs, and benefits of participation. Currently, there is a lot of confusion about TEFCA in the provider community. Elucidating the program will likely drive participation without burdensome mandates or penalties.

## V. <u>Improvement Activities Category</u>

## **Category Weight, Reporting, and Scoring**

ASCRS appreciates the consistency in category weight and reporting period for the Improvement Activities category for performance year 2023. We also strongly support CMS' decision to continue to award small practices double points for each improvement activity (IA).

Proposed Removal of IA PM 7 (Use of QCDR for feedback reports that incorporate public health) and

consolidation into IA\_PSPA\_7 (Use of QCDR data for ongoing practice assessment and improvements) ASCRS opposes CMS' proposal to consolidate several QCDR improvement activities into IA\_PSPA\_7, particularly IA\_PM\_7. Although we did not oppose a similar consolidation of QCDR IAs in the 2020 QPP Rule, the proposed consolidation in the 2023 proposed rule is more severe.

In line with CMS' current focus on SDOH, IA\_PM\_7 (Use of QCDR to generate regular feedback reports that incorporate population health, with a focus on vulnerable populations) is high-weighted. CMS is proposing to fold this important high-weighted IA under the umbrella of the medium-weighted IA\_PSPA\_7. This proposal would eliminate the high weighting of a health equity IA which directly contradicts CMS' stated emphasis on SDOH in the IA category. In order to consistently emphasize the importance of health equity, we recommend CMS either not finalize this proposal or to change the weight of IA\_PSPA\_7 to high.

## **Proposed IA Removals**

• Removal of IA\_PM\_7 (Use of QCDR for feedback reports that incorporate public health)

With CMS' new focus on SDOH, it is important that activities that collect SDOH information are high-weighted. IA\_PM\_7 (Use of QCDR to generate regular feedback reports that incorporate population health, with a focus on vulnerable populations) emphasizes this important goal. IA\_PM\_7 is currently high-weighted while IA\_PSPA\_7 is only medium-weighted. Thus, combining these improvement activities under IA\_PSPA\_7 would eliminate the high weighting of a health equity IA. To align with the importance of health equity and CMS' stated goal of assigning health equity related IAs a high weight, ASCRS strongly urges CMS to either not finalize the proposal to remove IA\_PM\_7 or to change the weight of IA\_PSPA\_7 to high.

#### VI. Advanced Alternative Payment Models (A-APMs)

#### Lack of Specialty-Specific A-APMs

ASCRS continues to recommend that CMS prioritize developing and implementing specialty-specific A-APMs. Currently, most A-APM models are primary care-focused. While some ophthalmologists participate in models, such as ACOs, they are generally not involved in the management of the ACO and are not always able to contribute much quality data to the Accountable Care Organizations (ACOs). A more frequent situation is that ophthalmologists do not have any A-APMs nearby to join, or local A-APMs do not include specialists. While we continue to believe that CMS should preserve a viable fee-for-service option in Medicare and the continuation of MIPS, because that is the best option for most ophthalmologists who provide surgical care on an episodic basis, there should be some A-APM options available to any ophthalmologist who wants to participate.

ASCRS also requests that the CMMI coordinate with the Physician-focused P-TAC and with specialty societies to seek and develop innovative voluntary payment and delivery care models. As we have previously indicated, several specialties have submitted A-APM proposals to the P-TAC, and P-TAC has recommended several of these models for implementation, but CMS and its Innovation Center have not followed through on any of those recommendations. Instead, CMS has pursued multiple new models largely centered, once again, on primary care. These models were not vetted by P-TAC, nor do they

incorporate the feedback the panel has suggested. This has led to widespread frustration and loss of confidence in the A-APM development process.<sup>3,4</sup>

P-TAC has been open to the proposals put forward by different specialties that would increase the opportunities for a wider group of specialties beyond primary care to participate in new models. Therefore, ASCRS continues to recommend, as we have previously, that CMS widen its approach, work with the specialty societies to develop innovative payment and care delivery model ideas which are voluntary and can be focused on conditions, and begin implementing those models for specialists.

#### RFI: QP Determination Calculations at the Individual Eligible Clinician Level

ASCRS is concerned with CMS' consideration of changing the Qualifying Participant (QP) determination to be solely at the individual clinician level as this will disproportionately, negatively impact specialists like ophthalmologists. One of CMS' stated rationales for considering this potential future policy change is that, by making APM-level QP determinations, they are unintentionally encouraging APMs to eliminate or limit specialist physician participation. This is because specialists furnish proportionally fewer services that lead to attribution of patients or payments to the APM Entity and, thus, are likely to lower the APM's threshold score. Primary care physicians, on the other hand, furnish proportionally more office visits which are frequently the basis for attribution of patients and payments. We agree with CMS' assertion that it is important for specialists to not be removed from APM Entities because specialists are an important part of the patient care continuum. However, we disagree that individual-level QP determinations are the best way to solve this problem, as it will not encourage specialists to participate in APMs.

CMS states that the methodology used in beneficiary assignment for the Shared Savings Program is "deliberately constructed such that assignment is largely based on primary care, rather than specialty care." ASCRS suggests that beneficiary assignment methodology should be redesigned to create a complete patient-centered care experience, including specialty care. Essentially eliminating specialists from the benefits of QP status because of a flawed attribution methodology is inappropriate and downplays the importance of specialty care in complete patient health.

#### **CONCLUSION**

In closing, we continue to be deeply concerned about the impact of the instability of the MPFS coupled with rising inflation rates, workforce shortage issues, and financial hardships due to the PHE on ophthalmic practices, many of which are small. Unfortunately, we are again bracing for steep Medicare reimbursement cuts in CY 2023, primarily due to budget neutrality adjustments that are a result of higher spending due to the increase in reimbursement for the standalone E/M codes in CY 2021. We urge CMS to apply the same increases for the standalone E/M codes to the E/M visits included in global surgical codes, and in particular for the cataract 10- and 90-day global surgical codes, as the post-operative visits were recently verified by multiple sources. In addition, we urge CMS to work with Congress to resolve the instability of the MPFS, which threatens physicians with annual cuts to their reimbursements and ultimately could impact patient access. CMS should request Congress provide a

<sup>&</sup>lt;sup>3</sup> https://www.medpagetoday.com/publichealthpolicy/medicare/83502

<sup>4</sup> https://aspe.hhs.gov/sites/default/files/private/aspe-files/207901/aspe-charting-future-directions-ptac.pdf

positive inflationary update to the conversion factor for Medicare in CY 2023 and thereafter to ensure stability in the MPFS for providers and their patients.

Additionally, ASCRS cautions CMS to consider all possible potential complications associated with performing cataract surgery in an office-based setting before establishing a non-facility payment rate. Cataract surgery remains the most common, albeit high intensity, Medicare surgical procedure, impacting millions of Americans, and our comments address major concerns and potential benefits associated with office-based surgery.

Finally, ASCRS thanks CMS for minimizing the number of substantial proposed changes to MIPS, particularly as we continue to deal with the repercussions of the COVID-19 PHE. ASCRS strongly urges CMS to make MVPs voluntary, alongside traditional MIPS, to allow providers a choice that best reflects their patient populations and practice needs.

Thank you again for the opportunity to provide comments on this proposed rule. If you need additional information, please contact Jillian Winans, ASCRS Senior Manager of Government Relations, at jwinans@ascrs.org.

Sincerely,

Doug Rhee, MD ASCRS President

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