September 13, 2021

Chiquita Brooks-LaSure, MPP  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard,  
Baltimore, MD 21244-1850

Submitted via: regulations.gov

Re: [CMS-1751-P] Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

Dear Administrator Brooks-LaSure,

The American Academy of Ophthalmology (the Academy) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the CY 2022 Medicare Physician Fee Schedule (MPFS) and the CY 2022 Quality Payment Program (QPP). The American Academy of Ophthalmology is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care.

Provided below is an executive summary of key points, comments, and concerns of the Academy regarding the coding and valuation policies within the CY 2022 PFS proposed rule. These comments are fully developed in the body of this letter along with additional issues and comments not highlighted in the summary.
Executive Summary

The Academy disagrees with several proposals in the MPFS that distort relativity in RBRVS and promote inequity among physicians under Medicare. In particular, we believe first and foremost, CMS should exercise its authority to do what it can to reduce the negative impact of policy changes on physicians providing care for Medicare beneficiaries. We are disappointed that CMS made no mention of applying payment equity to post-operative visits included in the global surgical payment, even after substantial advocacy from the surgical community. Ever since CMS announced the changes to evaluation and management (E/M) services in 2019, the Academy and many other surgical societies have objected to this decision not to apply it universally as they have previously. We believe CMS must apply the E/M payment increases to the post-operative visits in the global codes and provide equitable treatment to surgical specialties.

We are disappointed that CMS is proposing to only accept 76% of the total Relative-value Update Committee (RUC) recommendations for CY 2022. We urge CMS to continue working with the RUC as it is the most representative consensus of all medical specialties regarding physician work and expenses. While we are pleased to see that CMS has taken the expertise of the RUC for many of our Ophthalmic codes, we do urge CMS to consider the clarification and clinical expertise the Academy is providing in our detailed responses to proposals CMS has put forward on several ophthalmic procedures.

Additionally, we applaud CMS’ focus on health equity and believe there are several opportunities for CMS to reduce health disparities and improve care for Medicare beneficiaries through appropriate physician reimbursement and the use of innovative technologies. The Academy appreciates CMS working to ensure all communities have access to innovative sight-saving services and would particularly highlight our comments related to payments for pediatric ophthalmology surgery, remote retinal imaging, and glaucoma surgery.

We appreciate many of the MIPS flexibilities implemented by CMS in light of the ongoing PHE and hope that CMS will continue to consider flexibilities and delays for some of the proposals in the CY 2022 QPP. There are several policy proposals that will continue to create challenges for practices working to avoid penalties. Proposals, like measure removal, disadvantage clinicians in small and rural practices that are providing necessary care for patients. Many of the MIPS measures proposed for removal are vital metrics that could, if not implemented in practices, potentially do harm to patients. With CMS removing measures from the program and organizations unable to test and offer new measures to alleviate the strain for practices, at a minimum, CMS should delay removal of MIPS quality measures. Additionally, the Academy believes that registries qualifying for the Clinical Data Registry measure in the promoting interoperability performance category should have public health indications (separate from the state public health registries) similar to the requirements to be considered a QCDR.
In light of the ongoing PHE, the Academy urges CMS to continue to delay full measure testing for QCDR measures for an additional year while specialty societies and other QCDR vendors recover financially and shift back to priorities outside of the PHE. Finally, the Academy believes instead of overly complicated programs, physicians should simply be rewarded if they actively participate with benchmarking in a CMS approved EHR-based QCDR.

We appreciate the consideration of our detailed QPP comments and opportunity to work closely with CMS to ensure our practices can succeed in the MIPS program or other payment tracks such as MVPs or APMs. Please find our detailed comments for both the CY 2022 MPFS and QPP in the subsequent sections.
SPECIFIC ISSUES IN THE MEDICARE PHYSICIAN FEE SCHEDULE

CY 2022 NPRM Conversion Factor

For CY 2022 CMS has proposed a conversion factor is $33.58, a decrease of $1.31 from the CY 2021 conversion factor of $34.89. For more than 20 years, Medicare physician payments have been under pressure in response to efforts to reduce health care spending. Medicare physician payments have remained constrained by a budget-neutral financing system that lacks an automatic inflation related update mechanism similar to those in place for other Medicare providers such as hospitals and skilled nursing facilities. The conversion factor has failed to keep up with inflation and by 2030, under current policies, will be only about 50% of what it would have been if it had simply been indexed to general inflation starting in 1998.

We appreciate everything that CMS has done to help physician practices survive the COVID-19 pandemic and the actions taken by Congress last year to avert drastic cuts to Medicare payments scheduled for implementation in 2021. But as practices are still recovering from the pandemic and working to resume “normal” operations, now is not the time for drastic cuts to Medicare physician payments. The Academy is aligned with the AMA in asking that the 3.75% budget neutrality adjustment must continue to be waived in light of the ongoing PHE. We urge CMS to engage with Congress as they work to ensure appropriate reimbursements and improve the Medicare payment system and provide continued stability for physicians. At a minimum, CMS should exercise its authority to do what it can to reduce the negative impact of policy changes on physicians providing care for Medicare beneficiaries.

Global Payments

The Academy, in alignment with many other surgical specialties, strongly believes CMS must apply the increased 2021 valuation of the office E/M visits to the postoperative visits incorporated in the surgical global packages. This move is critical to maintain the relativity in the Medicare Physician Fee Schedule and to ensure that physicians are paid equitably for providing equivalent services. Additionally, organized medicine through the Relative Value Update Committee (RUC) has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values in the global codes. CMS, however, did not take this action and instead rejected the recommendation causing serious inequities in the 2021 physician fee schedule.

Ophthalmology services are a prime example of why CMS’ current policy to withhold payment equity for postoperative office visits in the global period is flawed. When RUC survey respondents provide their input on physician work required to perform a service, the postoperative visits are part of the RVU valuation recommendation. As such, during the cataract surgery revaluation in 2019, CMS agreed with the RUC that the global surgical payment period includes three postoperative visits for CPT 66984 (one level 2
and two level 3 visits). Given CMS’ acceptance of these visits, there is no reason why ophthalmologists should be paid less for E/M visits than other physicians who are providing the same level of service per visit. **Failing to adjust the global codes is equivalent to paying some physicians less for providing the same exact level of E/M services.** The Medicare statute specifically prohibits CMS from paying different physicians differently for the same work, and the “Secretary may not vary the . . . number of relative value units for a physicians’ service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.”

Failing to adjust the global codes is equivalent to paying some physicians less for providing the same level of E/M service.

It is critical that CMS increase the E/M portion of the global codes in the final CY 2022 Medicare Physician Fee Schedule because to do otherwise will continue to disrupt the relativity in the physician fee schedule. Changing the values for some E/M services, but not for others, disrupts the relativity mandated by Congress as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (P.L. 101-239), which was implemented in 1992 and refined over the past 27 years. In the past, every time the payments for new and established office visits were increased, CMS also adjusted the global surgery bundled payments to account for the increased values for the E/M portion of these codes. Additionally, we believe CMS decision conflicts with section 523(a) of MACRA. Through the Medicare Access and CHIP Reauthorization Act (MACRA), Congress required CMS to collect data on global codes. Notwithstanding this ongoing project, nothing in Section 523(a) of MACRA precludes CMS from making these equity adjustments to the global codes in the meantime.

Further, an extensive process exists to re-evaluate “misvalued” codes. **If CMS feels that specific global codes are “misvalued,” the agency should request the AMA’s RUC to review these codes to ensure the global payments accurately reflect the actual services and postoperative visits being provided to patients.**

Ophthalmology services are a prime example of why CMS’ current policy to withhold payment equity for postoperative office visits in the global period is flawed:

- **Retinal Detachment Surgery:** Many ophthalmic surgery codes have several post-operative visits included in the global payment. For example, when surgeons treat retinal tears on an emergent basis to prevent progression to retinal detachments that can cause permanent visual loss, payment is for the surgery itself and two post-operative visits included within the 10-day global period for the procedure. These global surgical codes are in the process of being revalued. CMS’ decision to value post-operative visits less than their equivalent office visits will result in surgeons receiving LESS pay for the physician work of the procedure AND the two post-operative visits than if the surgeon did the procedure for free and instead of

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1 https://www.ssa.gov/OP_Home/ssact/title18/1848.htm
submitting a claim for the surgery, billed only the two post-operative visits at the current rate for E/M office visits. This makes no sense and emphasizes why the policy must change. *Physician work is the main component of payment for surgical procedures. The other components are practice expense and malpractice insurance costs.*

- **Strabismus Surgery:** With many states basing their Medicaid reimbursement on Medicare values, 2022 payment reductions for strabismus surgery could affect access for vulnerable children, further exacerbating existing disparities in the diagnosis and treatment of pediatric strabismus. Untreated strabismus can lead to permanent loss of vision in one eye and loss of depth perception, limiting vocational opportunities for those affected. As a result of revaluation, strabismus surgery codes will see significant Medicare payment cuts, possibly ranging from 2% to 61%, going into effect in 2022. If CMS improves the Medicare payment of these global codes through equity adjustments to the built-in E&M post-operative visits, it will help mitigate payment reductions for Medicaid services that disproportionately affect vulnerable populations or the providers who serve them.

While we, along with the Surgical Care Coalition, believe the Agency should have made the adjustments to the global values in last year’s CY 2021 rulemaking rather than in CY 2022, but highlight that it would not be without precedent to address the valuation of global CPT codes in the subsequent year. After changes were made as part of the 1st Five Year Review of the PFS, CMS (then-Health Care Financing Administration (HCFA)) initially declined to apply the E/M increases to the globals. However, the following year, in the CY 1998 PFS final rule, the Agency directly stated, “Upon further examination of this issue, we are increasing the work RVUs for global surgical services to be consistent with the 1997 increases in the work RVUs for evaluation and management services.”

We strongly urge CMS to apply the CMS approved E/M payment changes to the E/M values that are a component of the global codes in order to maintain the relativity of the fee schedule congruent with the revaluation of the office and outpatient E/Ms.

**RUC Process and Integrity**

For CY 2022, CMS has accepted 76% of the total Relative-value Update Committee (RUC) recommendations. Nearly all of the direct practice cost recommendations for these services were accepted and will be implemented. AAO believes that the Medicare program benefits from the consensus effort at the RUC. The RVS Update Committee is the best representation of the House of Medicine. The RUC process is thorough with ample opportunities for deliberation. It is the work of this dedicated volunteer community of physicians who contribute time, energy and knowledge that make the RUC process a success that benefits the Medicare program and all practicing physicians by maintaining relative values between services. Medical societies, such as the Academy, expend significant resources and expense to gather data and bring their
recommendations forward. This process involves the review of data from statistically valid survey instruments, thorough vetting, and discussion both within the specialty’s clinical and valuation experts as well as the broader panel who have a thorough understanding of the time and intensity components of a service’s value. **We urge CMS to continue working with the RUC as it is the most representative consensus of all medical specialties.**

**Specific Ophthalmology Codes and Values**

The Academy urges CMS to consider the clarification and clinical expertise the Academy is providing in our response to proposals CMS has put forward on several ophthalmic procedures and services within the CY 2022 PFS.

**67141 and 67145 Retinal Detachment Prophylaxis**

CPT 67141 describes cryotherapy of a retinal tear typically in an adult without the presence of a retinal detachment, while CPT 67145 describes laser photocoagulation of a retinal tear typically in an adult also without the presence of a retinal detachment. **We appreciate that CMS accepted the work values and direct practice expense inputs recommended by the RUC.**

**67311, 67312, 67314, 67316, 67320, 67331, 67332, 67334, 67335, and 67340 The Entire Family of Strabismus Surgery Base and Add-on Codes**

These procedures are all designed to correct ocular misalignment by removing one or more extraocular muscles from their insertions, shortening, or repositioning them, and resuturing them to the sclera. While we appreciate that CMS has adopted the RUC recommendations for the family of eleven strabismus surgery codes (CPT 67311-67340) we are concerned with the impact of these dramatic reductions.

Seven of these services will be subject to greater than 20% reductions in the allowable from CY 2021 to CY 2022 at the proposed conversion factor of $33.5848. The affected procedures are CPT 67311, CPT 67314, CPT 67320, CPT 67331, CPT 67332, CPT 67334, CPT 67335, and CPT 67340. We note that CPT 67340 is not on the CMS list of “Codes Subject to Phase-In.” It should be because it is subject to a 21% reduction in the allowable. We feel strongly that the reductions for all seven of these services should be phased in to mitigate the potential impact on access associated with such large reductions.

Even with a phase-in, these represent major cuts to almost all the surgical codes used by pediatric ophthalmologists, a limited and shrinking group of physicians who are the only providers of these services. **Therefore, we also recommend that the phase-in be implemented over three years, with one third of the total**
reduction taken annually rather than the typical 19% reduction the first year. We also recommend that the phase-in be applied to CPT 67312 and CPT 67316 as well as the seven services noted above. Although the anticipated reductions for these two services are less than the typical threshold of 20%, they are greater than 10% and represent a significant component of patient care revenue for pediatric ophthalmologists.

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

Additionally, CMS has an opportunity to further mitigate the impact of these cuts by improving the Medicare payment of global codes through equity adjustments to the built-in E&M post-operative visits. With many states basing their Medicaid reimbursement on Medicare values, the 2022 payment reductions for strabismus surgery could affect access for vulnerable children, further exacerbating existing disparities in the diagnosis and treatment of pediatric strabismus. Untreated strabismus can lead to permanent loss of vision in one eye and loss of depth perception, limiting vocational opportunities for those affected. This equity would help mitigate payment reductions for pediatric strabismus surgeons providing Medicaid services that disproportionately affect vulnerable populations. We urge CMS to do all it can to ensure that the payment is fair and does not exacerbate current disparities. Data emerging during the pandemic on the status of pediatric ophthalmology practices indicated that these practices are under severe financial strain. Additionally, practices primarily treating Medicaid patients saw limited financial relief from the provider relief fund as other practices have due to the lower reimbursements under Medicaid. If CMS restores payment equity in the fee schedule, the estimated cut to CPT 67311 falls from 22% to about 14%. We urge CMS to apply this equity to postoperative visits.

68XXX Lacrimal Canaliculus Drug Eluting Implant Insertion

We appreciate and agree with CMS’ acceptance of the RUC-recommended work value of 0.49 work RVU.

CMS reduced the direct PE input for the ophthalmic screening lane time (EL006) from the RUC-recommended value of 9 minutes to 5 minutes. CA004 and CA0036 are not included in the standard equipment formula. We thank CMS for catching this error.
66174 and 66175 Dilation of Aqueous Outflow Canal

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

CMS proposed a work RVU of 9.34 for CPT 66175 “using a reverse building block methodology” but did not describe what CPT codes or work values were used to arrive at that value. We are therefore unable to specifically comment on the methodology CMS used. We agree that the RUC-recommended values and times place this code near the top of the intensity and complexity spectrum, which is appropriate for an intraocular procedure involving a 360-degree microscopic cannulation of Schlemm’s canal, a structure with a diameter of less than 20 microns in the typical glaucoma patient. In addition, we are concerned with CMS’ choice of CPT 15150 as an upper limit to support their proposed values. This skin graft procedure is much less intense and complex than an intraocular procedure and carries an IWPUT of 0.0237, far lower than any other intraocular procedure.

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

We appreciate that CMS 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 placement of the stent in the canal. We agree with CMS and with the RUC that the incremental work value is 1.72 WRVU, derived by subtracting the difference between the survey 25th percentile work values for CPT 66174 and CPT 66175. We recommend that CMS retain this 1.72 WRVU increment and apply it to the RUC-recommended work value for CPT 66175, recognizing the intensity of the intraocular work. Therefore, we request that CMS adopt the RUC-recommended value of 8.53 WRVU for CPT 66174.
66982 and 66984

We appreciate and agree with CMS’s reaffirmation of the values for CPT code 66982 and CPT code 66984.

66987 and 66988

As in previous comments, we urge CMS to adopt the RUC-recommended values for CPT 66987 (13.15 WRVU) and CPT 66988 (10.25 WRVU) rather than continued carrier pricing which is disruptive for beneficiaries and physicians. These values were arrived at by RUC methods based on robust survey results.

669X1 and 669X2

We strongly disagree with CMS’ proposed work values for CPT 669X1 (10.31 WRVU) and 669X2 (7.41 WRVU). These are substantially below the RUC-recommended values of 12.13 WRVU for CPT 669X1 and 9.23 WRVU for CPT 669X2, and do not appear to have a reasonable hierarchy.

These two new CPT codes describe ab-interno insertion of an aqueous drainage device performed in combination with cataract and intraocular lens (IOL) surgery. The increment in CMS’ proposed work values over the corresponding standalone cataract/IOL procedures’ work values (which CMS reaffirmed as correct in this Proposed Rule) are an inconceivably low 0.06 WRVU ($2.01 at the proposed conversion factor) and defy logical explanation or recognition of the necessary incremental work to the corresponding standalone cataract/IOL procedures, CPT 66982 and CPT 66984.

There can be no doubt that the insertion of the aqueous drainage device requires additional intraservice time (IST) compared with the IST of corresponding standalone cataract/IOL codes. As part of an intraocular procedure including cataract surgery, the stent insertion component is of similar or greater intensity and complexity than the standalone procedure. These eyes with glaucoma have additional medical problems which increases the intensity of the service. The intensity is increased even further when the procedure is performed in eyes with additional comorbidities beyond glaucoma that necessitate complex cataract surgery.

The combined procedures cannot possibly be almost identical in time to the standalone procedures. Inserting the drainage device requires substantial time over and above that required for the cataract/IOL surgery. The following steps are required in addition to and separate from the cataract/IOL surgery:
1. Deepen the anterior chamber with viscoelastic.
2. Apply viscoelastic to the corneal surface.
3. Apply a goniolens to the corneal surface.
4. Locate collector channels to identify sites for the drainage device insertion.
5. Lift the patient’s head off the head rest and rotate it 30 degrees away from the surgeon.
6. Rotate the operating microscope 30 degrees towards the surgeon.
7. Reapply the goniolens and adjust the microscope to visualize the chamber angle and nasal trabecular meshwork.
8. Insert the drainage device inserter through the main incision and across the anterior chamber towards the nasal chamber angle.
9. Retract the inserter protective sleeve to expose the drainage device.
10. Position the drainage device at the level of the trabecular meshwork and insert it into Schlemm’s canal.
11. Release the device from the inserter.
12. Tap the tip of the device to seat it firmly.
13. Observe for blood reflux.
14. Remove the injector.
15. Deepen the chamber with additional viscoelastic.
16. Repeat steps 8-14 with a second device inserted approximately 2 clock hours away from the first. (Insertion of two devices is typical).
17. Reposition the patient’s head vertically.
18. Reposition the operating microscope vertically.
19. Irrigate excess viscoelastic from the surface of the cornea.

The steps listed above, even in the hands of a fast, skilled, and experienced surgeon, take more than two to three minutes.

One reason that the survey IST for CPT 669X1 was shorter than the IST for the corresponding standalone CPT 66982 is that more experienced surgeons are currently performing the combined procedure and thus faster in their survey responses than would be typical. In addition, it is also the case that the maneuvers necessary in the performance of CPT 66982 and the cataract/IOL portion of 669X1 are more variable from patient to patient, resulting in variable ISTs for the complex cataract surgery component of 669X1. In contrast, intraoperative maneuvers required for CPT 66984, uncomplicated cataract surgery, and the cataract/IOL portion of the corresponding combined code CPT 669X2, are much less variable.

Thus, the surveyed IST for CPT 669X2 will be more consistent and more accurately reflect the true increment in time and physician work required to insert the device, than the surveyed IST for CPT 669X1. This is supported by comparing the survey IST ranges between CPT 669X1 and CPT 669X2. Ignoring
outliers and comparing the 25th to 75th percentile ranges for the two codes, the IST for CPT 669X1 ranged from 21 to 36 minutes, over a 3-fold difference. In contrast the 25th to 75th percentile range of ISTs for CPT 669X2 was 19 to 30 minutes, less than a 2-fold difference.

CMS’ use of a ratio of the survey total time results for CPT 669X1 to the total time for CPT 66982 would require an illogical and clinically impossible shorter IST for the combined procedure and is therefore flawed.

The inconsistency of the proposed work value with the agreed-upon similarity in intensity of the standalone and combined codes is highlighted when one calculates what the IST for the combined codes would have to be to maintain the IWPUT of the standalone code at CMS’ proposed work values.

For CPT 669X1, an increment of 0.06 WRVU equates to less than 1 minute of additional intraservice time. A more realistic 5-minute increase in IST for insertion of the device, as found in the survey for CPT 669X2, is also consistent with the intensity associated with the RUC-recommended value of 12.13 for CPT 669X1.

For CPT 669X2, CMS agreed with the RUC recommendation that an additional level 3 postoperative visit is necessary compared with the visits needed with the standalone procedure CPT 66984. Considering the time and work value of the additional postoperative visit, the 0.06 WRVU increment implies that insertion of the drainage device, again assuming an IWPUT the same as the corresponding standalone cataract/IOL procedure, reduces the intraservice time by 7 minutes. This is obviously an illogical conclusion.

Instead of using a ratio of total times for the complex code pair CPT 66982 and CPT 669X1, we urge CMS to accept the RUC-recommended work value of 12.13 WRVU for CPT 669X1. This is based on the 25th percentile magnitude estimation of physician work backed by a robust survey of 113 physicians who perform the procedure and are familiar with the work involved and is hardly a generous level. This valuation method is frequently employed by the RUC and often accepted by CMS as valid, and it is valid in this case.

While we agree with CMS and the RUC that the increment in work between the standalone cataract/IOL and the combined procedure is the same for both CPT 669X1 and CPT 669X2, CMS’ reliance on a flawed methodology to value CPT 669X1 is also carried forward into the proposed work value for CPT 669X2.

Instead, we urge CMS to use the RUC-recommended methodology, which is logical and clinically sound, to more accurately value CPT 669X2: Add the increment in work between the RUC-recommended value for CPT 669X1 (12.13
WRVU) and the corresponding standalone cataract/IOL procedure CPT 66982 (10.25, which CMS has reaffirmed) to the work value of CPT 66984 (7.35, which CMS has also reaffirmed), to obtain a work value for CPT 669X2 of 9.23 WRVU.

CMS’ current proposal results in an amount of physician work that is barely more than for standalone cataract surgery and will create access issues for patients needing critical sight-saving eye care. Glaucoma is the leading cause of irreversible blindness in the United States and has a disproportionate impact on black and Hispanic patient populations. Absent a cure, lowering IOP is paramount to slowing glaucoma progression. Topical eye drops are often used as the first treatment option for glaucoma patients, but some patients do not respond to pharmaceutical therapy and require other treatment options. Minimally invasive glaucoma surgery (MIGS) is an option that allows for the implantation of drainage devices during cataract surgery that lower and maintain acceptable levels of intraocular pressure. Following surgery, many patients require fewer or even no eyedrop medication to control their condition, which can reduce the costs associated with long-term medication requirements.

These proposed values are illogical and destroy the relativity between this family of procedures within the RBRVS. We urge CMS to accept the RUC methodology and RUC-recommended WRVUs which remains the most accurate means available for valuing the physician work associated with CPT 669X1 and CPT 669X2. If CMS does not accept the RUC-recommended values for CY 2022, then we strongly recommend carrier pricing of these codes until the time of the new technology review by the RUC.

92229 Remote Retinal Imaging AI

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

We also appreciate that CMS recognizes that practitioners incur resource costs for ongoing use of the software. The analysis fee is a direct practice cost analogous to a supply because it is attributable to a specific imaging service provided to a specific individual patient each time it is performed. It is not an indirect cost like computer hardware or software that is purchased once or licensed annually or monthly and then utilized repeatedly to provide varying services to multiple patients.
CMS’ publication of a national price for CPT 92229 will ensure appropriate payment nationwide. While we continue to support the RUC recommended direct PE inputs, including for the software analysis fee, CMS’ proposed crosswalk to CPT 92325 for PE offers a reasonable approximation and is superior to continued contractor pricing in terms of patient access to this innovative technology.

Additionally, in this proposed rule CMS is soliciting feedback on a variety of questions regarding coverage of AI and other innovative technologies. CPT 92229 Remote Retinal Imaging AI allows patients to immediately learn if they have an eye problem that needs attention while they are being seen by their primary care provider or others managing their diabetes. Because the AI device can identify diabetic retinopathy severe enough to threaten vision, it can speed up and increase completion of referral appointments for patients who need but would not otherwise obtain an ophthalmological examination. Further, this technology can be located in remote areas without easy access to a retinal specialist, it can facilitate this important annual check for diabetes, improving patient outcomes. Greater access to this technology is an important health equity issue, as significant health disparities exist in diabetes care and access to the diabetic eye exam.

Without sufficient reimbursement, medical and ophthalmology practices are unlikely to adopt this sight-saving advancement and patients across the country will be unjustly disadvantaged. To remove barriers in underserved communities and individuals, devices that promise a significant advance in public health should be accurately priced to ensure its widespread adoption. The Academy appreciates CMS working to ensure all communities and beneficiaries have access to innovative sight-saving technology.

Clinical Labor Updates

For 2022, CMS proposes to also implement new wage data from the United States Bureau of Labor Statistics to update clinical labor costs. These wage rates were last updated in 2002 and the updated data significantly increase the overall pool of direct costs. We understand the total direct practice expense pool increases by 30 percent under this proposal, resulting in a significant budget neutrality adjustment and while we agree that an update is needed, we are concerned that this is another example of the problem with budget neutrality and inadequate updates to the physician payment pool. The specialty level impacts illustrate that some specialties that perform high supply and equipment cost procedures in the office are particularly harmed by the budget neutrality provision of this proposal while other specialties with high labor costs benefit from the proposal.
The Academy supports CMS moving forward with the clinical labor update for CY2022. However, we ask that CMS Analyze their data and publish codes with the most significant impacts (positive and negative) much like the information provided for the supply cost update.

We also note that there are some outlier procedures with exceptionally high supply to clinical labor cost ratios that are disproportionately affected by this update. One case in point is CPT 65778, Placement of amniotic membrane on the ocular surface; without sutures. When performed in the office, the 2021 supply cost makes up 99% of the non-facility direct PE cost. The high supply cost appears to have resulted in a greater reduction in PE for 2022 than would be expected from a clinical labor update. We ask CMS to review the methodology for the update as applied to this procedure.

The Academy is concerned that the dramatic PE reduction associated with this update will result in an allowable that is less than the cost of procuring the amniotic membrane tissue. This will markedly reduce in-office access to this procedure for patients with sight-threatening ocular surface disease and might force these cases into the HOPD or eliminate availability of the procedure altogether. If there is no way to isolate the effect of the high supply cost, we ask CMS to phase in the reduction over four years, similar to the phase-in for the clinical labor update.

**Telehealth Provisions**

CMS is proposing to continue paying for services placed temporarily on the telehealth list through the end of 2023. Broadly, the Academy has been very supportive of proposals to expand telehealth coverage especially during the PHE when in-person visits have been particularly challenging. We do believe, however, that CMS should pay fairly, relative to other covered services, for any services that may be permanently added to the list of Medicare covered telehealth services.
MIPS Value Pathways (MVP)

Timeline

CMS is requesting public comment on CMS goal to sunset traditional MIPS after the 2027 reporting year. At this time, ophthalmologists and other physicians have no MVP option available and do not fit into most Alternative Payment Models (APMs). Without the option for traditional MIPS, this leaves ophthalmologists and other physicians without a reporting method to avoid penalties. If CMS were to move forward with eliminating MIPS, the Academy would need more information as to how CMS plans to handle clinicians that do not have MVPs or APMs available for reporting and what CMS plans to do to make it possible or these clinicians to avoid penalties.

Additionally, the Academy seeks additional clarification about the goal of the MVP reporting option and how it advances CMS’ aim to improve quality or transition clinicians into APM participation as originally intended. The MVP program, as it is proposed, mimics the traditional MIPS program with some key changes. It does not provide any elements that are specific to APM participation that would allow clinicians to become familiar with the requirements of a given APM. If the traditional MIPS program ceases after performance year 2027 and clinicians are encouraged or mandated to participate in APMs, they are not likely to be any more prepared to do so than they were prior to any participation in an MVP. As an effective transition stage into the APM program rather than MVPs, CMS should develop a program or element in an existing program that delivers participants regular and relevant feedback on cost metrics that prepares clinicians to take on financial risk.

The transition away from traditional MIPS does give CMS an opportunity to reconsider the recognition of EHR-based clinical data registries as an alternative pathway towards demonstrating value to the program. Participation in an EHR-based Qualified Clinical Data Registry (QCDR) provides real time, relevant feedback to clinicians who actively monitor their activity. QCDRs allow clinicians to compare themselves with national and inter-practice benchmark reports on their performance related to clinical care and patient outcomes relevant for their specialty and subspecialty. QCDRs help physicians monitor and manage patient populations, facilitating early interventions and preventive care, which can lead to more successful disease management and less expensive care. Clinician-led QCDRs collect specialty-specific meta-data that can be used to analyze treatment effectiveness in specific demographics, at specific stages in the disease process, and account for variables in a way that was not previously possible. This would allow researchers and clinicians to better identify and treat underserved communities which aligns with the Administration’s and CMS’ goal of improving equity in health care. Additionally, the end-to-end electronic transfer of data shows real world evidence of interoperability and contribution of health information to advance public health goals set by CMS. Many QCDRs now have published, peer reviewed data demonstrating the impact on quality improvement for patient care, MVPs must demonstrate the same effectiveness. The Academy believes instead of overly complicated payment programs, physicians should be rewarded if they participate in a CMS approved EHR-based QCDR.
Numerous published articles criticizing MIPS have also recommended that CMS just recognize clinical data registry participation instead. Such move is also aligned with the Congressional MACRA directive encouraging the use of registries.

**Foundational Layer (MVP Agnostic) Scoring**

CMS has proposed that at the time of registration for a group participating in an MVP, participants must choose a population health measure on which they will be scored. Starting in 2023, participants can choose between two administrative claims-based measures: Hospital-Wide, 30-day, All-Cause Unplanned Readmission Rate or Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions measures. The performance score achieved for either of these measures will be added to the total quality category score. While the Academy does not oppose this proposal, we have concerns about the impact for specialists and physicians with few or no hospital admissions like Ophthalmologists who should not be scored on these measures. While there is a path in place to exempt the physicians for whom there is insufficient data for these measures, we want to ensure that CMS' attribution process is reasonable and accurate, in order to avoid penalizing physicians who are not responsible for a patient's inpatient care.

**Quality Performance Category Scoring**

In this rule, CMS has proposed that MVP quality performance category scoring policies would align with those used in traditional MIPS and the quality measure benchmarks will be based off existing MIPS measure benchmarks when available. The Academy supports CMS' proposal to use existing benchmarks and believes that creating new benchmarks for MVP participants could unfairly disadvantage clinicians in the traditional MIPS program by crediting them with fewer points for being further along in the topped-out measure lifecycle. In addition, for specialties and clinicians that do not have MVPs available to them, it would be unfair to provide benefits to performance scoring that they are not eligible for.

**Quality Performance Category**

**QPP117: Diabetes: Eye Exam**

CMS has proposed a revision in the measure guidance for QPP117: Diabetes: Eye Exam that states “The eye exam must be performed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation." The Academy recommends that a qualification be added to this revision requiring that an AI interpretation must be generated by an FDA-approved system to qualify. CMS has proposed this revision to update the guidance to allow for the use of artificial intelligence as it is applicable and clinically appropriate for numerator compliance for this measure. Additionally, CMS has proposed that the measure numerator note is revised to include the statement "Alternatively, results may be read by a qualified reading center that operates under the direction of a medical director who is a retinal specialist." The Academy believes that to maintain consistent and clarity, the measure guidance should include the CMS
For the 2022 performance year, CMS has proposed the removal of 19 quality measures. This is a substantial number of measures proposed for removal and will have significant consequences for practices attempting to avoid penalties in CY 2024. Clinicians need to be able to report measures that are clinically appropriate and for many practices, especially those in small, rural practices, the removal of quality measures can inhibit their ability to reach the minimum measure requirement. Even large practices with EHRs will see a negative impact depending on the specialty or subspecialty. For example, QPP317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented allows for many specialists to reach the required six measures. Without measures that span specialties and can be collected without EHR, CMS is disadvantaging small and rural practices that are providing necessary care for patients.

CMS has proposed the removal of measure QPP317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented partially due to being a process measure. However, there are other process measures in the MIPS program that CMS is not proposing for removal. While CMS is moving towards the prioritization of outcome measures, process measures are still necessary and appropriate for inclusion in the MIPS program. CMS should reconsider the proposal to remove process measures like this one that have not reached topped out status.

In recent meetings with CMS, agency staff confirmed that the new administration is no longer focused on reducing the number of quality measures in the MIPS program but ensuring that the appropriate and necessary quality measures are included in the program. The Academy believes that many of the measures proposed for removal are vital metrics that could, if dropped from a medical practice’s evaluation and monitoring, result in harm to patients from an undetected decline in performance on those measures. This could reduce coordination and communication between primary care providers and specialists and impede progress towards public health goals of reduced visual impairment in the elderly population. For example, the removal of measures QPP14: Age-Related Macular Degeneration (AMD): Dilated Macular Examination and QPP19: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care have consequential implications. Blindness due to diabetes and AMD are prominent public health concerns. These measures call attention to the importance of HbA1c control for maintaining good vision and comprehensive eye exams for those with non-neovascular (dry) AMD before they progress to neovascular (wet) AMD, facilitating early detection and intervention to reduce vision loss.

Additionally, because of the COVID-19 Public Health Emergency (PHE) in 2021, measure developers, qualified clinical data registries, medical societies, and others have had to delay measure development and testing. With CMS removing measures from the program and organizations unable to test and offer new measures to alleviate the
strain for practices, at a minimum, CMS should delay the removal of MIPS quality measures for one year. This will allow QCDRs time to provide their users with better options. This will also allow a grace period for practices still feeling the grave effects of the PHE such as lowered patient volumes, shortages of staff, financial difficulties, and diminished administrative help that are needed to navigate the loss of longstanding MIPS quality measures. With the penalty at 9%, this is a weighty threat to practices that are trying to remain open during the pandemic and would cause severe financial stress that could cause them to pull away from Medicare or close their practices.

Data Completeness

The Academy supports CMS proposal to maintain the current data completeness threshold at 70% for CY 2022. For practices without an EHR, it is incredibly burdensome to meet the data completeness threshold manually and the Academy appreciates CMS’ efforts to not increase burden for these practices. However, in 2023, CMS is proposing to increase the data completeness threshold to 80%. The Academy requests the rationale for the increasing the data completeness threshold and what, if any, data CMS is basing this decision on.

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

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

Quality Measure Scoring

New Measures

Beginning in calendar year 2022, CMS proposed to establish a 5-point floor for the first two performance periods for new measures if 1) a measure benchmark could be created or 2) where a measure benchmark could not be created but the case minimum and data completeness criteria were met. The Academy supports this proposal and thanks CMS for providing scoring incentives for new measures to be reported. In the past, it has been difficult to create benchmarks for new measures because of the scoring limitations like the 3-point floor.
Removal of 3-point Floor

CMS has proposed the removal of the 3-point floor for measures with a benchmark (except for new measures), without a benchmark (except for small practices), and that do not meet the case minimum (except for small practices). The Academy supports these proposals and thanks CMS for maintaining leniency for small practices that often have difficulty achieving higher quality scores.

Removal of Bonus Points

CMS is proposing to remove bonus points for reporting additional outcome and high-priority measures and the end-to-end reporting bonus.

The removal of bonus points will discourage the use of EHR reporting and outcome measures, contrary to the direction that CMS have been pushing practices towards for years. As the MIPS program gets harder, practices need more assistance in achieving the threshold to avoid a penalty. In 2022, the threshold to avoid a penalty will significantly increase at the same time as the number of points available for practices to earn decreases. Between topped-out measures, the dropping of the 3-point floor, the decreased quality category weight, and the removal of bonus points, high-performing practices previously succeeding in MIPS will struggle to earn an incentive or even avoid a penalty.

The ability to offer clinicians an incentive to report measures through end-to-end reporting sets vendors, such as QCDRs furthers the goal of the program and provides more usable real-world data. These end-to-end electronic reporting bonus points and bonus points for outcome and high-priority measures also encourage clinicians to sign up with QCDRs. Using the data collected for public health purposes which is the definition and goal of QCDRs. The Academy urges CMS to reconsider the proposal to remove high priority and outcome measure bonuses and the end-to-end electronic reporting bonus.

Cost Performance Category

Experience Report: Cost Measure Performance Transparency

We ask CMS to provide transparency on cost measure performance. We would ask that this includes any trends on services or coding which cause variation in the cost measure score. Currently, practices are provided no usable feedback on their cost measure performance that allows them to make real-time or future changes to improve. If CMS were to provide cost measure performance transparency, practices may be more willing to participate in APMs with shared risk if they had more experience and understanding of how their actions effect cost performance.
Promoting Interoperability (PI) Performance Category

Automatic Reweighting of PI for Small Practices

Beginning in CY 2022, CMS is proposing an automatic reweighting of the PI category for small practices. While the Academy applauds CMS' continued flexibility for small practices and believes the small practice hardship option for the PI category is necessary, we do not agree with CMS' proposal to automatically reweight the category for small practices. This proposal removes an incentive for practices to move towards the adoption of EHRs which has been CMS' goal for many years. As stated above, with the removal of end-to-end electronic reporting bonus points, CMS is departing from the recent messaging that encourages a broadened digital landscape. In line with CMS' messaging, the Academy has also been pushing our membership towards EHR adoption to comply with MIPS reporting and the increasing requirements to avoid a penalty. **Because of this, the Academy has concerns that this proposal sends the wrong message to practices newly adopting EHRs and practices with EHRs who have been diligently working to meet the requirements of this category. We believe the burden and additional requirements of reporting may limit the adoption of EHRs.**

Public Health and Clinical Data Exchange Objective

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

Additionally, the Academy believes that registries qualifying for the Clinical Data Registry measure should have public health indications (separate from the state public health registries) similar to the requirements to be considered a QCDR. As stated by CMS, QCDRs are run by organizations such as specialty societies, certification boards, or regional health collaboratives that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. In the Meaningful Use program, from which the PI category was derived, the receiving entity was required to declare readiness to accept data as a specialized registry and use the data to improve population health outcomes. These limitations and requirements should apply similarly to the Clinical Data Registry Reporting measure to ensure that clinicians are receiving credit for participating in registries benefiting the medical community and the public at large.

Provide Patients Electronic Access to their Health Information Measure
CMS is proposing to modify the Provide Patients Electronic Access to Their Health Information measure to require patient health information to remain available to the patient (or patient authorized representative) to access indefinitely, starting with a date of service of January 1, 2016. The Academy has concerns over how this proposal will affect practices who have not been on EHR since January 1, 2016. We ask CMS to clarify if this requirement still apply. Additionally, this may be difficult for practices who have changed EHRs during that timeframe and thus lost access to data when contracts ended. **Instead, the Academy suggests amending the proposal to require patient health information remain available indefinitely dating back to the first date that the data became available in the EHR. Hardship exemptions should be available to providers whose EHR vendors have ceased operation or have had significant operational shutdowns over the years.**

The Academy also has concerns regarding the extensive requirements for this measure. In the measure specifications, CMS states that patient health information needs to be made available to each patient for view, download, and transmit within four business days of the information being available to the clinician for each and every time that information is generated whether the patient has been "enrolled" for three months or for three years. A patient who has multiple encounters during the performance period, or even in subsequent performance periods in future years, needs to be provided access for each encounter where they are seen by the MIPS eligible clinician. The patient cannot be counted in the numerator if the MIPS eligible clinician does not continue to update the information accessible to the patient each time new information is available.

Effectively, if a practice had a technical issue for a few days or a chart was not transmitted to portal within four days for any reason, those patients would be excluded from the numerator for the entire reporting period even if the patient’s other visit data were transmitted on time. The strict mandates to meet this measure penalizes clinicians who may be following the requirements but face issues outside of their control. The Academy has seen practices struggling to achieve higher scores on this measure for reasons such as technical issues that are resolved outside of the four-day window provided by the measure. Additionally, there is a requirement for practices to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's certified electronic health record technology (CEHRT). However, certain vendors charge fees to implement the API and subsequently have technical, implementation, and rollout challenges. **For these reasons, the Academy urges CMS to reduce some of the restrictions on this measure to allow leniency for clinicians working through issues beyond their control while providing patients access to their health information.**

**Performance Threshold/Payment Adjustment**

In CY 2022, CMS is proposing to raise the performance threshold to 75 points. An additional performance threshold would be set at 89 points for exceptional performance. While we are glad to see that there will likely be a bigger bonus pool due to budget neutrality, we would appreciate more detailed information on how different specialties and practices would be impacted. **The Academy would appreciate CMS**
projecting future payment adjustment amounts, which may give societies a stronger argument for their membership as to why clinicians should continue to fully participate in MIPS.

**QCDR Measure Testing**

The Academy appreciates all of our recent conversations with CMS regarding the issue of QCDR measure testing and CMS' willingness to listen to our concerns. QCDRs have limited resources especially following the PHE and need adequate time and guidance from CMS to ensure success. **In light of the ongoing PHE, the Academy urges CMS to continue to delay full measure testing for QCDR measures for an additional year while specialty societies and other QCDR vendors recover financially and shift back to priorities outside of the PHE.** Currently, full testing is required to begin for the 2023 QCDR submission process which is due in September 2022. Regarding QCDR measure testing, the Academy supports the proposals provided by the Council of Medical Specialty Societies (CMSS). Specifically, we echo the suggestions that CMS:

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

The Academy requests that CMS provide clarification and guidance on what testing will be required to satisfy the QCDR testing requirements. It would be beneficial for QCDRs and measure stewards to be able to review testing protocols with CMS prior to testing to ensure that CMS will approve to avoid wasted expenses. Because of the looming measure testing requirements, many societies have dropped or are considering dropping their QCDRs qualification for their registries leaving many specialists without clinically relevant measures.

**MIPS Exclusions by Reason and Specialty**

In the CY 2017 Quality Payment Program final rule, CMS provided a table for MIPS exclusions by reason and specialty for the MIPS transition year. The table breaks down the exclusions by the percentage of clinicians in a specialty excluded from MIPS by low volume, qualifying APM participants, and newly enrolled to Medicare. Since the publication of this chart, the low volume threshold has changed, and the MIPS program has been in effect for five years. The Academy urges CMS to consider sharing an updated table that shows the rate of participation in MIPS for specialties. As ophthalmology has one of the highest percentages of participation in MIPS, it is helpful for medicine and policy makers to understand how this regulation effects eligible practitioner participation rates.
Extreme and Uncontrollable Circumstances (EUC) Hardship

The Academy supports CMS continuing to offer the optional EUC hardship for practices affected by the COVID-19 pandemic. Although the COVID-19 pandemic continues to affect some practices across the country in terms of patient volume, staffing, and financial issues, this has not been uniform across all medical practices. Thus, an automatic extreme and uncontrollable circumstances hardship exception is not appropriate for the 2021 reporting year.

Alternative Payment Models

The Academy has concerns with CMS’ approach to APMs. While incentives for clinicians to participate in APMs is clear—5% bonus on payment, CMS has not provided reasonable pathways to participate. Currently, APMs are not a viable pathway for ophthalmology, particularly subspecialists. Most existing APMs are focused on primary care or hospital-based care which does not allow for ophthalmologists’ and other specialists’ participation. Because there is not a direct path for many clinicians to participate in APMs, resources should be dedicated to designing and implementing models that are inclusive of clinicians outside of hospitals. CMS staff could work closely with Centers for Medicare & Medicaid Innovation (CMMI) and specialty societies to develop models that fit the needs of a given specialty.

Additionally, because there are few opportunities for specialists to participate in APMs, the Academy believes that Congress will need to extend the current 5% annual bonus to continue to incentivize physicians to develop and participate in Advanced APMs. These bonuses are only authorized by MACRA through the 2022 performance year and therefore specialists who have not been afforded the opportunity to participate have been disadvantaged.

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In conclusion, we appreciate the opportunity to comment on the Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements proposed rule. The Academy is committed to protecting sight and empowering lives by setting the standards for ophthalmic education and advocating for our patients and the public. If you have questions or need any additional information regarding any portion of these comments, please contact Kayla Amodeo, PhD, Director of Health Policy at kamodeo@aoa.org or via phone at 202-210-1797. Again, the Academy would like to thank you for providing us with the opportunity to comment and to work with CMS. We look forward to ongoing engagement and stakeholder input.

Sincerely,
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