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Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Mr. Slavitt:

The American Academy of Ophthalmology, the Academy, is submitting our comments on the CMS proposed rule regarding the Merit-based Incentive Payment System (MIPS) under the 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

The significant level of work that CMS undertook to bring this rule forward is undeniable. We appreciate the opportunity to provide our input on CMS' extensive proposal to implement a new payment program that moves from a payment method that was focused primarily on fee-for-service to one that realigns payments based on the overall value of services provided to beneficiaries. The Academy along with most of the healthcare community supported the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the repeal of the Sustainable Growth Rate formula.

The Academy is dedicated to working with CMS to ensure a successful implementation of MACRA. Our members will be significantly impacted under this new environment especially given that ophthalmology has the highest Medicare penetration than any other specialty other than geriatrics. In addition, ensuring that small practices are able to succeed under MACRA is critical to ophthalmology because half of ophthalmologists practice in groups with five or fewer physicians. Our members agree with the CMS goal of eliminating redundancies and streamlining the existing separate programs around quality, use of certified EHRs and resource use. We also agree with CMS' assessment that the vast majority of physicians will begin

this new payment era under the MIPS program. These comments will focus on the Merit-based Incentive Payment System (MIPS), its four components (quality, ACI, CPIA and resource use) and its performance composite scoring mechanism. **A summary of our recommendations, concerns and comments are found in Appendix A which accompanies this document.**

With Alternative Payment Models (APMs) being the long range CMS goal for how providers are paid, we continue to have difficulty determining a path for surgical specialty care to fit into APMs based on our review of the proposal. In a separate comment letter, we will provide our thoughts on provisions that could be changed in order to broaden APMs that would include more physicians and surgical specialties like ophthalmology that serve a large Medicare population. At a minimum, though, **CMS should follow the Congressional intent to immediately facilitate patient-centered medical homes as Advanced APMs.**

We realize that with the NPRM not coming out until late April 2016 and a final rule not expected until later this fall, it will be challenging for providers, and organizations, both federal and those representing physicians, impacted by this new system to prepare for a January 1, 2017 start date. While a delayed performance period would aid preparation, we understand the trade-offs would create inequities for ophthalmologists and other specialties under the quality portion of MIPS—the largest component of the Composite Performance Score (CPS).

Many quality measures are specified around a 12- month reporting period. If CMS delays the start of MIPS to July, such measures would not be an option for reporting, as they require a full year performance period. Further, smaller sample sizes due to a shortened reporting period would negatively impact the physicians' performance rate for these measures.

Additionally, in ophthalmology we have six surgical-based measures that cannot be reported after September 30 each year because of the three month (90-day) follow up required in order to determine the surgical outcome for reporting. A July start date would mean that for anyone reporting those measures will only have a performance period of three months which would also significantly impact their ability to be successful.

- **If CMS does decide to implement a July start date for MIPS performance, we request a continued one-year performance period or that accommodations be made that would minimize the negative impacts caused by a shortened performance period such as smaller sample size, bias or variable benchmarking for these important outcome measures.**

All medical organizations with extensive materials, tools and other educational opportunities provided by CMS should work to get the word out about MACRA and the QPP. The Academy has an excellent track record of providing the tools, guidance and education needed to help our members succeed in previous value-based programs such as PQRS,

Meaningful Use and the Value-based Modifier and we stand ready to do the same in order to implement MACRA.

The Academy and other medical specialty societies are willing and eager to assist the Agency in outreach efforts. CMS has worked exceedingly hard to educate the provider community about this proposed rule. We ask that CMS continue to expand an open and continuous dialogue with practicing clinicians and medical specialty societies to identify unintended consequences of this new program as early as possible.

If it becomes evident that clinicians are not collecting or reporting data correctly as a result of a lack of understanding of program rules, we ask CMS to consider solutions, including holding clinicians harmless in the initial year of the program. While we recognize that this approach would limit the ability to award bonuses, we believe that clinicians should be scored based on their clinical performance, rather than how well they are able to understand these new and complex requirements. **The Academy recommends that together, CMS, medical specialty societies, practicing clinicians and practice administrators continue to refine these policies so that they truly support clinically-focused innovations in the delivery of high quality, high value patient care.**

Clinical Data Registries—A Key Tool in Quality Measurement and Value-based Healthcare

The Academy has a longstanding commitment to quality improvement, and is a leader in the development of measures evaluating the quality of eye care, as well as patient outcomes. The Academy has invested significant resources in measure development, which is a lengthy and expensive process. In 2009, the Academy formed the initial Eye Care Workgroup within the American Medical Association's Physician Consortium for Performance Improvement to develop quality measures, and later developed clinical outcome measures and patient-reported outcome measures for cataract surgery. Through that work, the Academy developed 12 quality measures, eight of which were endorsed by NQF and are included in PQRS, four of which were not endorsed by NQF but are not in the PQRS measure set. The Academy also developed the first PQRS measures group for cataract surgery, which contains four outcomes measures, including the patient satisfaction and validated patient reported outcomes measures developed by the Academy.

In collaboration with our ophthalmic subspecialty societies, the Academy developed 18 new subspecialty outcomes measures - including seven retina measures - which were approved by CMS for reporting through the Academy's Qualified Clinical Data Registry, IRIS® Registry in 2015 PQRS. Most recently, the Academy developed a second measures group addressing diabetic retinopathy, which CMS included in the 2016 PQRS program.

Building on its commitment to quality improvement, the Academy launched the American Academy of Ophthalmology IRIS® Registry

(Intelligent Research in Sight) in April 2014. IRIS® Registry is an important quality improvement tool that enables ophthalmologists to improve patient care, manage patient populations, benchmark their individual performance and that of their practice, and enhance quality and practice efficiency. Additionally, IRIS Registry provides many ophthalmologists with a way to successfully participate in and meet the increasing demands of the federal quality reporting and incentive programs.

The Academy appreciates that CMS has publicly recognized this type of registry and in this proposed rule that clinical data registries are providing significant contributions to a value-based healthcare environment. We see many areas in the rule where registries such as IRIS® Registry will be able to play an important role for our members participating in MIPS and supporting them in providing the highest quality of care for their patients.

- **Strengthening and encouraging the development of on clinical registry platforms should be one of CMS' major priorities, and we encourage CMS to take even more steps to incentivize physicians and recognized those who choose to participate in these entities.**

The Medicare Access and CHIP Reauthorization Act of 2015 calls on the Secretary to encourage the use of registries in implementing MIPS. To fulfill this statutory obligation, CMS is proposing to allow QCDRs to report data on three of the MIPS categories, provide bonus points to QCDR reporters who electronically report quality measures, allow QCDR participation to count for multiple CPIAs, and provide one bonus point to MIPS participants in the ACI category that participate in a specialized registry.

However, the Academy is concerned that these proposals do not offer sufficient encouragement. **We recommend additional policies that will further encourage the use of QCDRs:**

- **Reduce the reporting burden for QCDR participants under the quality performance category by lowering the data completeness standard from 90 percent of patients from all payers to 50 percent of Medicare patients, and by allowing QCDRs to report on measures groups.**
- **Increase the weight of all CPIAs that involve participation in a clinical data registry or QCDR to “high”, each worth 20 points.**
- **Allow EHR-based participation in a specialty-led clinical data registry by MIPS participants to qualify for full credit, or at least full-base score credit under the ACI category.**

More details on these and our substantial recommendations on the MIPS NPRM are outlined in the applicable sections of this comment letter.

I. Merit-Based Incentive Payment System Policies

A. MIPS Participant Identifiers

The Academy appreciates CMS' efforts to simplify the identifiers used to track participation in federal reporting programs. Under the current federal reporting programs, participating physicians have been identified in various ways. The variation in identifiers used across the current programs causes significant confusion and administrative burden to providers. Having one identifier to track participation in all of MIPS will help to reduce some of this confusion.

For practices that choose to participate in MIPS at the group level, CMS is proposing to use the group's billing tax ID number as the MIPS identifier. However, CMS is proposing to use a combination of billing TIN and national provider identifier number as the identifier to assess performance of ECs participating in MIPS as an individual.

The NPI/TIN combination is currently used in PQRS, and this dual identifier has led to confusion and increased burden, especially among physicians practicing in more than one location. With this identifier, a physician that practices under two or more TINs would have to meet the MIPS requirements for each instance, with a score then weighted for activity under each TIN. Likewise, if a practice has multiple office locations including in multiple states, that practice may have multiple TINs. Even though the physicians that practice in the various locations are the same, they would be required to meet the quality reporting requirements at each location. This places a burden on these physicians and practices that is not experienced by those with just one TIN. We ask CMS to ensure that physicians that practice in more than one location, and groups that operate practices with different TINs are not unfairly disadvantaged or burdened by the proposed NPI/TIN MIPS identifier.

B. Exclusions

The Academy appreciates CMS' proposal to exclude certain clinicians from MIPS, and supports the categories for which exclusions are offered. The Academy seeks clarification on how the MIPS exclusions for ECs would apply to groups that report at the TIN level. In evaluating a group's MIPS performance at the TIN level, the Academy urges CMS to remove excluded physician's data from the TIN's data so that it would not skew the practice's MIPS performance. For example, in a group of 5 physicians where one physician meets the low volume threshold exclusion and the other four are subject to MIPS, the excluded physician's data should not be aggregated with the remaining physicians' data if the

practice chooses to report MIPS at the TIN level. Additional comments specific to the proposed MIPS exclusions are below.

1. Newly Enrolled Physicians

CMS proposes to exclude ECs who newly enroll in Medicare within PECOS during the reporting year. While the Academy agrees that these ECs should receive an exclusion from MIPS, we recommend that CMS extend the exclusion for an additional year so that sufficient time can be provided for these physicians to acclimate to their practices and begin participation in MIPS. The Academy recommends that at a minimum, CMS exclude physicians for an additional year who enroll in Medicare in the last half of the year preceding the performance year. These physicians are at a disadvantage compared to those who sign up earlier in the year and who have more time to learn about the program and its requirements.

2. Low-Volume Threshold

CMS also proposes an exclusion for ECs that meet the low-volume threshold. CMS proposes that ECs or groups that have Medicare billing charges less than or equal to \$10,000 and provide care to 100 or fewer Part B-enrolled Medicare beneficiaries meet the low volume threshold and would be excluded from MIPS. **The Academy recommends that CMS raise the minimum threshold to \$30,000 and exclude physicians that exceed either the dollar or patient cap.** By raising the threshold in Medicare allowed charges and eliminating the cap on the number of unique Medicare patients seen by the physician, CMS would better assist small practices or those that currently see few Medicare patients from the burdensome reporting requirements. AMA has reported that this option would exclude approximately one quarter of physicians, while still subjecting more than 95 percent of allowed spending to MIPS.

In addition, The Academy believes there should be some flexibility to account for providers who minimally exceed the threshold, for example, those who bill charges just over the dollar or patient cap. These providers should not be required to comply with MIPS when they exceed the threshold by a minimal amount. **We recommend that CMS allow for flexibility so that providers are not burdened by MIPS penalties when they slightly exceed the low volume threshold.**

C. Group Reporting

With the exception of large groups using the GPRO Web Interface reporting options or groups reporting the CAHPS survey for MIPS, CMS is proposing to eliminate the group registration process for those that use a third party entity to submit MIPS data to CMS. CMS explains that it is able to discern from the submission made by a third party whether the data submitted represents a group submission or an individual submission. **We support this proposal to remove the group registration requirement.**

The current GPRO registration process for PQRS has been confusing and problematic. In the past, some groups have registered for GPRO without fully understanding what it was, when they actually wished to report PQRS as individual EPs. In addition, some groups wishing to use the GPRO reporting method have selected GPRO reporting options not applicable to their groups, such as GPRO Qualified Registry, when they actually intended to report GPRO Certified EHR Technology. This has caused reporting problems, and has also led to inappropriate assessment of penalties on groups that did meet quality reporting requirements, but did so through a different reporting mechanism than what they registered for. **Therefore, we applaud that CMS is removing the group reporting registration process.**

D. Virtual Groups

It is disappointing to the Academy and others that CMS is not able to implement virtual groups in the first year of MIPS. While we understand that technological barriers prevent CMS from doing so, and we appreciate that the agency is taking the time needed to implement it in a way that is workable from the onset, we believe that a delay in virtual groups will disadvantage practices that cannot on their own meaningfully achieve success under the MIPS program.

Virtual groups were created to level the playing field by allowing small providers and practices of various specialties and subspecialties to group report under the law without issues of ownership that are common in group reporting today. In fact, the requirements for the virtual group in part rely upon “a combination of tax identification numbers” which would allow providers to remain autonomous while enjoying the benefits of group reporting. Such an option can be especially helpful to providers with limited patient interaction, providers in rural areas, smaller practices, and those who, through no fault of their own, are not able to report on the full set of measures, including certain sub-specialists. It was not the intent of Congress, however, to limit such a provision as serving only small group practices.

The statutory requirements related to virtual groups allow for individual providers to report and be measured as a group against a set of robust measures if they conform to the requirements under

the law. It is important to note that the requirement to establish virtual group reporting is tied to “a performance year”, the first of which is 2017. **Establishment of the virtual group reporting option for the 2017 performance period would go a long way to addressing concerns of many medical specialties that see no ability to adopt an APM in 2017 under the proposed rule and fear limited measure availability will hurt their scoring under the MIPS program.**

We encourage CMS to continue to work on the needed technology infrastructures so that virtual groups may be implemented as soon as possible. In the meantime, steps can be taken to establish this option as a means of facilitating group reporting for those unable to meaningfully report. In doing so, CMS should pay particular attention to facilitating medical specialty adoption in areas where measure availability is not enough to achieve full reporting absent the ability of the Secretary to re-weight the performance categories or measures within such categories. This option was put forward by Congress as a way for small group practices to band together to meet the requirements of MIPS at a group level. Virtual groups would allow small practices to have the same reporting advantages enjoyed by larger groups.

E. MIPS Hardship Exception

The Academy asks CMS to consider implementing exceptions from penalties for providers who are unable to participate in MIPS due to a significant hardship. For example, in the rule CMS seeks comment on how to account for MIPS ECs that have extended leave from practice that may affect their measure sample sizes because they only see a few number of patients throughout the year. The Academy believes that a hardship exception must be set up for providers in this situation. We have assisted many of our members who because of illness or weather-related catastrophes have had practice interruptions that would be devastating under MIPS. There should be additional exceptions available to providers who face hardships, similar to the hardship exceptions that exist under the Meaningful Use program, including natural disaster, financial hardship, and technology vendor issues. CMS should also implement an exception for providers nearing retirement age.

F. Proposed Data Submission Mechanisms for MIPS ECs and Groups

The Academy appreciates that CMS is proposing a broad number of mechanisms that providers can choose from for submitting data to meet the requirements of the various components of MIPS. It is important for quality reporting that claims-based reporting remain an option available to MIPS participants. Many providers have relied on this reporting mechanism and are familiar and comfortable with reporting in that way. They should be permitted to continue reporting their quality

data by claims if that is the mechanism that works best for their practice and workflows. We also appreciate that CMS is proposing to allow registries to submit Clinical Practice Improvement Activity and Advancing Care Information data to CMS for eligible clinicians and groups. We think such reporting will be useful to eligible clinicians and groups for registries to serve as a primary platform for and simplifying MIPS reporting.

However, we note that many physician societies including the Academy dedicated their limited resources to develop costly registries as a way to enhance quality and patient outcomes, and improve their professions through the use of data. Helping providers to meet federal quality reporting requirements was a secondary benefit to registry participants. However, supporting physician regulatory compliance has become the priority for many registries given the increasingly complex and challenging regulatory requirements faced by providers. **We ask CMS to simplify what is required of registries when they submit MIPS data and to provide support and detailed guidance to registries in order to minimize their reporting burdens on behalf of physicians.**

In 2014, the Academy launched the IRIS Registry to advance clinical discovery, improve quality and enhance patient outcomes. Today, the majority of U.S. Academy members rely on IRIS Registry to meet the requirements of the various quality reporting programs. The proposed rule will have a significant impact on registries like IRIS, including on what services they offer, and the Academy asks CMS to recognize that time, budgets and resources are limited. CMS seeks comment on whether or not health IT vendors and registries should be required to have the capability to submit data for all applicable MIPS performance categories in the first year of the program. We strongly believe that CMS should not require this of registries in the first year of the program.

These third party entities should have the option, but not be required to have the capability to submit data for all MIPS applicable performance categories, especially in the first year of the program. More time may be needed for these entities to develop these new functions, and furthermore, some entities are better equipped to perform certain functions. For example, registries are better positioned to report on quality measures, but EHRs may be better to report on ACI data. The Academy believes these entities should have the option to submit EC and group data for all applicable MIPS categories.

CMS is proposing to require qualified registries and QCDRs to submit their applications to CMS by January 15 during the reporting year. We ask that CMS permit registries to declare later in the reporting year if they are capable of submitting MIPS data to CMS for the various MIPS categories. At this point in time, and especially in the first year of the program, registries may not know if they will

be able to support data submission for CPIA or ACI, as these functionalities are new for registries. Because data submission is not required until the following year, **CMS should allow registries to declare later in the performance year if they plan to support data submission for each of the MIPS categories.**

G. Small Practice Technical Assistance Funding

MACRA provides funding for technical assistance to small practices with fewer than 15 MIPS eligible clinicians, in addition to eligible clinicians in rural areas, and practices located in geographic health professional shortage areas (HPSAs). The law calls on the Secretary to enter into contracts or agreements with appropriate entities to offer guidance and assistance to these MIPS eligible clinicians. The Academy understands that CMS recently announced this funding opportunity. However, we would like to underscore the significant role that professional societies and medical specialty societies play in providing guidance and offering assistance to their clinician members in understanding, complying with, and doing succeeding federal quality reporting programs such as MIPS. **35 percent of Academy members are solo practitioners, and the average ophthalmology practice size is five physicians. The majority of ophthalmology practices have fewer than 15 MIPS ECs and would greatly benefit from the small practice technical assistance funding provided under MACRA.** Our members are already accustomed to seeking this assistance from the Academy. This would be similar to most other larger healthcare provider membership organizations.

- **We request that CMS reserve some of the technical assistance funding for specialty societies such as the Academy so that we can more effectively provide specialty- specific guidance to our members in small practices and rural settings.**

II. MIPS Quality Performance Category

CMS envisions a future state where MIPS eligible clinicians will be seamlessly using their certified health IT to leverage advanced clinical quality measurement to manage patient population with the least amount of workflow disruption and reporting burden. However, the Academy points out that clinical data registries such as the Academy's IRIS Registry are already fulfilling this vision. Using IRIS Registry, physicians who previously had to click several times in their EHR to record an eCQM no longer need to do this. By knowing where the physicians document certain data elements within their EHR, IRIS Registry can find and use that data to calculate performance on important patient outcome measures, and provide feedback to providers in close to real time. **Therefore, we ask CMS to better leverage and encourage the use of**

such registries in finalizing the requirements of the quality performance categories.

A. Quality Composite Requirements

The Academy applauds CMS' efforts to increase flexibility and reduce burden for physicians participating in MIPS. **We are pleased that CMS proposes to lower the required number of quality measures on which physicians must report.** We are also glad that **CMS is proposing to do away with its requirement for reported measures to cover three quality domains,** as that often resulted in physicians having to report on less relevant measures simply to comply with that requirement. In addition, we are very **pleased with the flexibility introduced by CMS in allowing physicians to get credit for the measures that are reported,** even when they report fewer than six. Allowing providers to earn partial credit increases flexibility and allows providers to be rewarded for achieving high quality on the measures that they report for MIPS.

- **The Academy has concern that the six measures required for reporting is still too high.**

Six appears to be an arbitrary number. Many providers will not have six relevant measures to report. CMS says it plans to have a process in place similar to the MAV to account for providers that do not have six applicable measures to report, but this process is not detailed in the rule. **It is important that relevant stakeholders have the opportunity to learn about and comment on the future MAV process prior to it being finalized.** Additionally, **the Academy urges CMS to reduce the minimum number of measures required for initial reporting from six to three, which would be more achievable for the majority of providers.**

1. Measures Groups

We are extremely disappointed that CMS is proposing to eliminate PQRS measures groups. This proposal would significantly hurt small practices and solo practitioners, particularly those without an EHR. **The Academy strongly encourages CMS to reinstate measures groups in the final rule as a reporting option to satisfy the MIPS quality requirements.**

Measure groups are important to quality measurement, as they are designed as composite measures to provide an overall picture of patient care for a particular key medical condition or set of services. For example, the current cataract measure group addresses surgical complication rates, clinical outcomes, patient-reported outcomes, and patient satisfaction to provide a comprehensive picture of surgical care. The initial measures that were included in this

measures group underwent a deliberative process with the intent of the measure group in mind.

As another example, the diabetic retinopathy measures group helps to address a significant public health problem by allowing for the comprehensive evaluation of provider performance and patient outcomes related to a disease that threatens the eyesight of a very large population, and supports improvements in quality of care and outcomes related to diabetic retinopathy. This is a new measure group for 2016 for which the first reporting year is only half completed. It is very concerning that such a new and promising measures group will be summarily dismissed for 2017 without an opportunity to gauge its value for diabetic patients.

In Table 64 of the proposed rule, CMS provides data that show small practices and solo practitioners will be disproportionately negatively impacted. These numbers will be even more negative if CMS finalizes this proposal to eliminate measures groups. Many small practices do not have the resources to adopt an EHR, but still want to participate in quality reporting. Measures groups offer a lower burden while maintain a relevant and meaningful way for individual providers to meet the quality reporting requirements.

Removing measures groups eliminates an important quality measurement tool from the federal quality reporting system, reduces reporting options available to providers, and increases the reporting burden on providers, especially for solo practitioners and small practices without an EHR. In addition, measure groups incentivize ECs to attempt the more challenging and in some ways more burdensome, outcome and patient experience measures.

The Academy believes it is unfair to remove this reporting option for individual eligible clinicians, but to maintain the GPRO Web Interface reporting option for large groups. The GPRO web interface option is similar to measures groups because it enables large groups to report on a sampling of their patients. Group practices using the GPRO web interface reporting mechanism are only required to report on 248 patients, which is a small sample for groups of this size. While this sample is larger than the 20 patient minimum required for individuals utilizing the current PQRS measures groups, GPRO web interface reporters must have at least 25 physicians in their practice, and only individual practitioners may report on measures groups. Currently in PQRS, QCDRs cannot report on measures groups, and instead, measures groups must be reported using qualified registries. This is a misalignment that results in administrative burden on registries, which as a result

are required to obtain multiple registrations from CMS. Therefore, we encourage CMS to allow QCDRs to report on measures groups under MIPS. Allowing QCDRs to develop, collect and report on measure groups would improve overall patient care pertaining to associated conditions or procedures. **The Academy strongly encourages CMS to maintain measures groups as a quality reporting option under MIPS, including the cataracts and diabetic retinopathy measures groups, and to allow QCDRs to report on measures groups for their participating physicians.**

2. Data Completeness Standard

The Academy is opposed to CMS' proposal to require physicians using all quality reporting mechanisms except for claims reporting to report on patients from all payers, rather than only Medicare patients. In addition to this new requirement, CMS is also proposing to increase the number of patients a provider or group must report on from 50 percent to 80 percent for claims reporters, and to 90 percent for qualified registry and QCDR reporters. The Academy believes these proposals are unreasonable and will prevent many providers who make good faith efforts to succeed from doing well under MIPS. **We ask CMS to significantly lower the proposed data completeness standards.** In finalizing MIPS, the Academy urges CMS to set more focused and achievable reporting requirements so as to not punish physicians who are making good faith efforts to succeed, and so that meaningful improvements can be accrued to quality and patient outcomes from a more concentrated and targeted effort.

The proposed data completeness standards would add significant reporting burden to providers under MIPS, particularly to providers that do not have an EHR, and would be very challenging to meet. When a practice does not have an EHR, they have to report via claims or manually enter data into a registry in order to meet the requirements of quality reporting. Reporting by claims for 80 percent of Medicare patients, or manually entering data into a registry on 90 percent of patients across all payers would be an **overwhelming burden for any practice. It essentially would preclude physicians without an EHR from participating in quality reporting. Not only would this set them up for failure in MIPS, it would discourage them from participating in quality reporting at all.** CMS should not discourage providers from participating in MIPS by establishing impossible thresholds. CMS should ensure that all providers, including those without an EHR, have a reasonable opportunity to participate and do well. To ensure

this, CMS should reduce the data completeness standards for claims, qualified registry and QCDR reporters to no more than 50 percent of Medicare patients.

CMS proposes that MIPS participants must meet the data completeness standard for each measure reported in order to get any points for their performance on that measure.

However, **reporting on such a high percent of patients isn't necessary to accurately and reliability assess a provider's quality performance.** For example, a provider achieving a 100 percent performance score on six measures reported for 50 percent of applicable patients should not earn a 0 for the quality performance category because he or she fails to report the six measures on 90 percent of patients. Moreover, the Academy believes that it is especially unfair that large groups reporting quality measures using the GPRO Web Interface option are permitted to report on 248 consecutively ranked Medicare patients. Groups of that size are not required to report on patients from all payers. This places them at an advantage over smaller practices who would have to meet a significantly higher data completeness standard under this proposal.

Finally, the Academy points out that requiring physicians to report on such a large proportion of patients discourages the development and use of important patient reported outcomes measures. A statistically significant sample size would be more practical. For example, QCDR participants using the Academy's IRIS Registry could not report two patient experience measures: 303, Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery, and 304, Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery measure. These measures require patient surveys, and it would be far too burdensome for a provider to survey such a high percent of their patients. Patient reported outcomes and patient satisfaction are important aspects of surgical care, and there is high demand among consumers and other stakeholders for patient experience measures. Under MIPS, CMS should encourage providers to report these measures by lowering the data completeness standard, and enabling providers to report on a small sample of patients for patient-experience measures.

3. Outcome Measures

The Academy applauds CMS for considering intermediate outcome measures as outcome measures under MIPS. This is a very helpful change in policy that recognizes the importance of intermediate outcomes. Intermediate

outcomes are especially important in evaluating some chronic diseases, such as glaucoma. The primary outcome for this disease is the prevention of vision loss, but intermediate outcomes such as reduction in intraocular pressure are important and more feasible to measure.

The Academy supports CMS' prioritization of patient outcome measures, and has developed over 20 outcome measures over the past few years which are now being reported through IRIS Registry's QCDR. However, even with these measures, **there are still many ophthalmologists, particularly sub-specialists, that do not have an outcome or other high priority measure to report.** Our concern is that these providers will be unfairly disadvantaged in their CPS because there are not any outcome measures relevant to their scope of practice, despite their willingness to report on one if they had the option.

As a result, these physicians will not have the opportunity to earn bonus points for reporting additional outcome measures. This will especially impact small practices where there is only one specialty or sub-specialty represented. Large practices often include multiple specialties and sub-specialties, and have more relevant measure options to choose from. Therefore, this is another component in MIPS which disadvantages small practices, particularly when there are limited outcome or other high priority measure available for reporting.

4. GPRO Web Interface Reporting

CMS is proposing that groups of 25 or more choosing the GPRO Web Interface option report the measures within the set on 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample. However, **the measures included in the GPRO Web Interface measure set do not apply to most specialists.** In these groups, specialists' performance and the quality of care they provide is not readily available to consumers. To improve the measurement of specialists that practice in these large groups, the Academy recommends that **CMS require or provide extra points when specialists practicing in groups utilizing the GPRO Web Interface option participate in their specialty's clinical data registry when applicable.**

B. MIPS Quality Measures

1. Specialty Measure Sets

The Academy lacks clarification around the specialty measure sets. We believe these sets are simply a way of displaying measures to ease the measure selection process. However, we are worried that these sets may be the new clinical clusters for the MAV process under MIPS. **There are 15 measures in the ophthalmology measure set, and there is no ophthalmologist for whom every single measure applies. There are many subspecialties in ophthalmology, and the Academy believes that CMS should create subspecialty measure sets for each of these subspecialty areas, and at minimum for diseases of the retina, cataract and glaucoma.**

Additionally, the Academy strongly urges CMS to exclude the two patient experience measures, 303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery, and 304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery from clinical clusters developed for the MAV process. We further ask that CMS consider requiring a smaller threshold for these measures. It is unreasonable and costly for a provider to survey 90 percent, or even 50 percent of their patients. **The Academy asks for measures 303 and 304 CMS permit providers to report them on a sampling of patients, such as 20 patients which is often the minimum elsewhere in MIPS, and that those measures be excluded from the MAV process.**

2. Eye Care Measures

For three eye care measures included in the MIPS measure set, 385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery, 387: Cataract Surgery with Intra-Operative Complications - Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy, and 389: Cataract Surgery: Difference Between Planned and Final Refraction, the Academy and the American College of Healthcare Sciences are both listed as measure stewards. The American College of Healthcare Sciences was originally a co-steward with the American Association of Eye and Ear Centers of Excellence. However, the Academy has taken over stewardship completely of these measures.

- **The American College of Healthcare Sciences is not a steward of these measures and should be removed from this listing.**

3. Claims-based Population Quality Measures

The Academy cautions that the claims-based quality measures proposed for the MIPS program are not relevant to the care provided by ophthalmologists. These measures include the Acute and Chronic Ambulatory Care – Sensitive Condition Composite Measures, and the 30-Day All Cause Readmission Measure. These measures evaluate all cause hospital readmissions and hospitalization rates for certain acute and chronic conditions. The flawed attribution methodology currently used in the VBM program and proposed for MIPS assigns patients that do not see a primary care provider to specialists based on the number of E&M services provided. Ophthalmologists often provide a significant number of E&M services to their patients because of the chronic conditions they treat, including diabetic retinopathy, age-related macular degeneration and glaucoma, and, therefore, are often attributed a significant number of patients. However, the care that ophthalmologists provide to patients does not relate to these claims-based quality measures proposed for MIPS. Very rarely is a patient admitted to a hospital as a result of ophthalmic care.

- **Therefore, we request that CMS exclude ophthalmologists from these measures and reweight the reported measures so that no points would be lost.**

C. Quality Scoring

The Academy applauds CMS for eliminating the “all or nothing” design of quality reporting, and allowing providers to earn points on each measure they report, even when they report fewer than six measures.

1. Benchmarking

We also support CMS’ proposals to publish benchmarks for quality measures prior the start of the reporting period. It is important for providers to know what benchmark they are being compared against so that they can track their performance throughout the reporting year. However, we are concerned that for new measures, the benchmark used for comparison will be based on data obtained during the reporting year. This is not transparent and would unfairly force providers to “fly blind.” This policy would discourage providers from reporting on new outcome measures due to the uncertainty around the benchmark. Therefore, we encourage CMS to allow providers reporting new measures to earn the full 10 points in the measure’s first year. This would encourage providers to report on new, perhaps more challenging outcome measures.

In setting performance standards and benchmarks for comparison, the Academy believes that CMS should take into account a provider's specialty and subspecialty, patient population, and reporting mechanism. Therefore, **we are pleased that CMS proposes to develop different benchmarks based on the data received by each of the different reporting mechanisms.** The Academy believes that reported performance varies based on the reporting mechanism used. EHRs have shown to be inaccurate and are unreliable for Reporting in some cases, and claims based reporting can be overstated. To account for variances in performance caused by reporting mechanism, we support CMS' proposal to establish different benchmarks for each reporting mechanism. We further encourage CMS to also set benchmarks to account for a provider's specialty.

2. Topped Out Measures

The Academy is pleased that CMS did not propose to remove measures which it considers to be "topped out." Doing so would have removed nearly half of all measures in the MIPS measure set, leaving providers with few measure options relevant to their patient populations. The Academy is opposed to removing measures from federal reporting programs when they appear to be topped out, as studies show that doing so results in a drop in performance. A study published in the British Medical Journal found that removing "topped out" quality measures from incentive programs can lead to a decline in quality.

According to the study, "Policymakers and clinicians need to be aware that removing financial incentives from clinical indicators may mean that recorded performance levels, and therefore potentially patient care, may decline over time." (Lester H, Schmitt diel J, Selby J, et al. The impact of removing financial incentives from clinical quality indicators: longitudinal analysis of four Kaiser Permanente indicators. *BMJ* 2010;340:c1898.)

CMS proposes a separate and different scoring method to be used for measures that CMS deems to be "topped out". We do not support moving forward with such a proposal. As proposed, providers earning a 100 percent performance score on a topped out measure would not be able to earn the full 10 points for that measure, despite their excellent quality performance. It is not fair to punish providers when they have excellent quality performance because, through no fault of their own, the measures are topped out. A provider should be rewarded for continued performance, and have the opportunity to earn full credit for having high quality, regardless of whether or not the measure is "topped out."

Large group practices with multiple specialties represented may have the ability to select different measures that are not topped out. However, small single-specialty practices do not have the same flexibility, as they are limited by the quality measures relevant to the care they provide.

- **The proposed benchmarking method for topped out measures will disadvantage many of these small practices that have fewer measure options. We ask that CMS not implement this policy which would hurt providers delivering high quality care, and instead we recommend that CMS use the same benchmarking methodology for all measures regardless of their performance level.**

3. Bonus Points

We support the proposal to provide MIPS participants two bonus points for reporting on additional outcome and patient experience measures other than the one required, and one bonus point for other high priority measures, and for each measure submitted with end-to-end electronic reporting. We believe these bonus points will encourage providers to select high priority measures and to utilize electronic reporting when feasible. We ask CMS to provide these bonus points for QCDR measures that are not included in the MIPS measure set but that are outcome, patient experience or other high priority measures, and QCDR measures that are not in the MIPS measure set but that are submitted with end-to-end electronic reporting. It appears that this is CMS' intent, but we ask CMS to clarify this.

While eCQMs are reported to CMS using the QRDA format, QCDR (non-MIPS) measures are reported using the XML format. However, these QCDR measures, though reported on XML, can allow providers to comply with CMS' proposed end-to-end electronic reporting standard and earn the bonus point when the data used to calculate the measures is electronically extracted from the EHR, and the measure is calculated electronically and reported to CMS on the XML. We strongly encourage CMS to allow providers reporting QCDR measures (non-MIPS) to earn the electronic bonus point when they meet the criteria for end-to-end electronic reporting.

However, we question how CMS will discern if a reported QCDR measure qualifies for the electronic reporting bonus because it would be reported on the XML format just as non-electronic measures would be. We suggest that CMS

could ask QCDRs to note whether or not the submission meets the criteria for the electronic reporting bonus during the submission process.

Finally, CMS is seeking comment on whether to cap the bonus points at 5 percent or 10 percent of the total possible points, and **the Academy believes that 10 percent would be more effective at encouraging the use of those types of measures and electronic reporting.** A higher cap would allow practices to earn more bonus points and would provide further encouragement to report on high priority measures.

III. Resource Use Performance Category

Measuring resource use is an important goal. Under the CMS Value-based Modifier (VBM) program the Academy has commented and discussed many problems that are associated with VBM and its associated Quality and Resource Use Reports. Paramount in those concerns are the faulty attribution of patients and insufficient risk adjustment. CMS is also now proposing to utilize 41 new Episode Groupers as part of this performance category including one for Cataract with IOL Implantation. We expressed significant concerns about this grouper in our February comments to the RFI and reiterate them later in this section. There are fundamental problems with attribution, risk adjustment and using groupers which were not created with stakeholder support and only recently with any input that has yet to effect change. These groupers have not been tested openly, and no information has been shared about any experience CMS has gained from utilizing them in the value- based modifier supplemental QRURs.

In view of all of these problems, the Academy recommends that CMS use the flexibility allotted in the statute to lower the overall weighting of this category.

- The statute says that Resource Use should carry a maximum weight up to 10 percent for the first year. Congress intended to provide flexibility to the Secretary in the weighting of the performance category, and we believe that a weight of no more than five percent is more appropriate. CMS should realign the other portion to either the Clinical Practice Improvement or Advancing Care Information categories or distribute it to both.
- Additionally, until CMS has overcome the serious flaws we have pointed to in our comments, the Method B cataract grouper should not be utilized.

In the proposed rule, CMS indicates that under this MIPS category measurement will be adjusted for geographic payment rate adjustments which is an important factor that should be taken into account.

Additionally, CMS also says that it will take into account beneficiary risk factors. We did not find any further details in the rule about risk adjustment. Similar to the VBM we expect that CMS will use the Hierarchical Condition Categories (HCC) with their Predictive Ratios (PR) to group patients at least for the beginning of the program. As described in other CMS documents referenced in the rule, the only way that CMS measures the PRs of beneficiaries within HCCs is based on dual status, aged/disabled status, and community/institutional status.

The Academy has in numerous in past rulemaking comments pointed to many problems with using the HCCs for physician risk adjustment. We note that CMS has acknowledged that significant problems have been raised about the HCCs, and in response it proposed an early release of revisions to the HCCs for use in the Medicare Advantage and Shared Savings Program. CMS should indicate whether the revised changes to the HCCs when finalized in February 2017 will be used for risk adjustment for the MIPS Resource Use Category. CMS has yet to publish any patient condition groups along with the newly released episode groups. Further, CMS has only just provided its RFI on patient relationship codes which are also open for comment and the Academy will be providing further input.

- **The Academy believes that appropriate Resource Use aligned with quality measurement is possible. A process whereby major national medical organizations such as the Academy would work together with CMS and other stakeholders to create resource use measures that are risk adjusted, appropriately aligned with available quality measures, and fairly attributed should be created.**

There is a better way to measure resource use that would simplify, streamline and carefully align such efforts with quality improvement, a key goal CMS has emphasized. Clinical data registries hold great potential to improve the accuracy of resource use data. There are numerous specialty society electronic clinical data registries in existence and many more expected to come on line soon. The IRIS Registry is an electronic registry that not only has access to clinical data collected from the electronic health record, but also has access to the practice's administrative database. Many other registries have the same capability. Through IRIS Registry, many practice expenses, visits, procedures, testing, pre-operative evaluations, lab results, and returns to the operating room are accurately and completely captured. This makes it possible to appropriately measure resource use for many common ophthalmological diseases and conditions using registry collected data.

In the proposed rule, CMS is also indicating that it wants to lower the minimum patient threshold for some resource use measures from the current 125 procedures as required for the value-based modifier to just 20 procedures.

- **The Academy strongly disagrees with such a proposal. The higher numbers ensure greater statistical reliability for the**

measure and offset the impact of outliers. Ophthalmologists and other providers should not be subjected to invalid, unreliable small sample sizes that these lower thresholds would establish.

A. Total Per Capita Cost Resource Use Measures

- **We do not support the Total Per Capita Costs measure as currently used because the risk adjustment methodology continues to be problematic, attribution strategies are unreliable, and the measure does not appear actionable by smaller groups.**

Payment Standardized Total Per Capita Costs uses the Hierarchical Conditions Category model (HCC) for risk adjustment. We do not believe that the HCC model, which was developed for the Medicare Advantage program adequately accounts for risk for purposes of analyzing physician group resource use. The HCC was designed to risk adjust large patient populations for insurance rate determination and was never designed for group or individual EP evaluation. For example, the HCC considers patient factors such as age, gender, prior year diagnoses, and Medicaid dual-eligible status. We do not believe that Medicaid dual-eligible status alone adequately captures differences in patient risk due to socioeconomic factors.

We continue to have concerns with the reliability of the measure. According to the NQF Steering Committee's report, the measure has acceptable reliabilities for groups of 25 or more EPs, and reliability increased with group size. However, nearly half of all Medicare physicians practice in groups of fewer than ten EPs. The NQF Steering Committee also noted concerns with the usability of the measure. The measure currently excludes outpatient pharmacy costs, which can be significant cost drivers in the Medicare population. It has also been the Academy's experience that physicians, in particular specialists, do not find the measure to be readily actionable when presented with their data. Outpatient prescription drugs play a growing role in the treatment of many diagnoses relative to other medical and surgical interventions. Yet, this measure does not include outpatient pharmacy costs in the measure calculation.

According to the Agency for Healthcare Research and Quality, 90 percent of seniors and 57 percent of non-elderly adults had a prescription drug expense in 2010 (Agency for Healthcare Research and Quality. Prescription Medicines-Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment: United States, 2010). The exclusion of prescription drug costs has the potential to skew resource use data such that patients receiving procedural interventions demonstrate higher resource use than patients taking maintenance medications, even

when the reality could be quite different. We note that the measure does include physician-administered drugs paid for under Medicare Part B and inpatient drugs paid for under Medicare Part A, further complicating the analysis.

Resource use data generated in the calculation of Payment Standardized Total Per Capita Costs is of limited value to physicians when presented without correlation to an appropriate quality measure. The Academy has gone to great length to develop a significant number of QCDR measures, and those should be utilized in CMS' determination of resource use. Without doing so, it is impossible to know whether resource use is high because the patient population is sicker than average or because of overuse.

CMS indicates that for future years that it would consider including measures that were based on Appropriate Use Criteria (AUC) and/or Choosing Wisely guidelines in the resource use category if they are developed through a multi-specialty, clinician led process. We agree that such measures would be helpful but seek clarification on what is meant by a multi-specialty led process. The Academy believes that a national medical association that has significant measure development experience and whose membership includes a variety of subspecialty interests would certainly qualify to develop such measures. Furthermore, clinical data registry such as the IRIS registry will be able to provide significant data on both quality and costs that will enable us to build such resource use measures.

- **The Academy has plans to develop new appropriate use measures addressing two Choosing Wisely guidelines, including the prescription of antibiotics for pink eye that is caused by adenovirus, and the provision of topical antibiotics before or after injections into the vitreous cavity of the eye. Once developed, these measures would serve as relevant appropriate use measures that are meaningful and applicable to contemporary ophthalmologic practice. These measures will be more appropriate measures of resource use for ophthalmologists and should be included in MIPS in future years.**

Evaluations of the existing resource use measures in VBM demonstrate that the feedback data are difficult for physicians to understand, not related to their scope of practice and not actionable.

Physicians have been presented with the total per capita costs for their patients and a comparison to their specialty peers in past QRURs. Feedback we received from physicians suggests that it was not always clear that the majority of cost data included in the report represented charges performed by other physicians that the patient saw in the course of their care.

In other cases, it was very clear that ophthalmologists have been attributed with costs over which they had no control and for which they did not contribute any patient care. Examples include the costs associated with treating urinary incontinence, an incarcerated hernia, chronic obstructive pulmonary disease and the significant costs of hospice care have been erroneously attributed to ophthalmologists. **Clearly these conditions are not at all related to the eye care provided by ophthalmologists, and are costs that could not have been controlled through increased coordination between the ophthalmologist and other physicians.**

B. Medicare Spending Per Beneficiary (MSPB) Resource Measure

- **The Academy is concerned that the Mean Spending Per Medicare Beneficiary (MSPB) measure also has significant and similar attribution problems as the Total Cost of Care measure. MSPB is not readily actionable and it fails to link to measures of quality of care. For these reasons, we do not support the measure.**

With the MSPB, any index inpatient hospitalization costs are attributed to the TIN that provides the plurality of Part B allowed charges. Again, with the number of chronic eye conditions in the Medicare population, it would not be unheard of for an ophthalmology practice to provide the plurality of Part B services for a beneficiary who may have also had a completely unrelated inpatient hospitalization. This is especially true since any outpatient procedures/costs will be included as part of the dominant Part B services.

C. Episode-based Measures Proposed for Resource Use

The Academy previously submitted to CMS its substantial concerns in February about the Method B Resource Use Measure for Cataract including pointing to incorrect trigger codes that have no diagnosis of cataract associated with them. From our review of Method B as well as the other episode groupers now released by CMS, it is clear that no practicing ophthalmologist reviewed or was involved in the final products.

Previously when CMS first explored the use of episode groupers in the Medicare population, it concluded that the existing groupers being used in the private payer community were not appropriate for the Medicare because they failed to adequately risk adjust for that population. In our review of the current proposed Cataract Method B episode grouper, we think the same inherent problems exist and that new problems have been added such that it should not be implemented as a measure of resource use.

1. Surgical Episodes of Care: Cataract with IOL Implantation

Cataract surgery is one of the most common surgical procedures covered by Medicare. (CPT 66984, 66982) The care and costs associated with the surgery, while appearing relatively easy for CMS to identify, may be complicated by several issues. These include preoperative testing (medical and surgical), IOL power determination and purchase, physician charges (surgeon and anesthesia), facility charges and drug charges. To date no reliably risk adjusted cataract episode grouper has been published.

In the proposed cataract episode grouper, CMS included known comorbidities that are excluded from all of the quality measures developed for cataract extraction. Not excluding such comorbid conditions with their anticipated complications will create an incentive for physicians to refer more complex/sicker patients to tertiary care centers. Ophthalmologists with high utilization will likely avoid the problem of adverse risk selection, while those in rural settings or in tertiary care centers where the most complex cases are managed will be unfairly penalized.

There are quality measures available for cataract with IOL surgery, including five specific cataract measures and one patient reported measure currently. Each of these can be reported separately by individuals, but the following eight measures together comprise the cataract measures group, which currently can only be reported for PQRS by qualified registry option. **The Cataract Measures Group should be aligned with this episode grouper. This is another reason why this and other measures groups should be retained under MIPS.**

Measure 130: Documentation of Current Medications in the Medical Record

Measure 191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Measure 192: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

Measure 226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Measure 303: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

Measure 304: Patient Satisfaction within 90 Days Following Cataract Surgery

Measure 388: Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule requiring unplanned vitrectomy)

Measure 389: Cataract Surgery Difference Between Planned and Final Refraction

2. Specific Issues with the Method B Cataract Grouper

We encourage continued collaboration and transparency in your efforts to shape episode groupers for resource use measurement. We see a number of problems with the information provided regarding the cataract grouper. We remain concerned about the lack of transparency and communication that has occurred with this process. There have been substantial changes made to the groupers based on our understanding of the previously contracted work. Transparency and collaboration would have provided more background and better informed our comments. **Based on what we currently see in the details provided there are problems regarding the codes that would trigger a cataract episode grouper.**

a. Incorrect Codes Placed into the Grouper

There is a Category III code, 0308T Insertion of ocular telescope prosthesis including removal of crystalline lens. This is an inappropriate code to be included in any cataract grouper. This procedure is the implantation of a device which is quite sizeable within the eye. It includes significantly more resources because of the cost of the implant, and the extensive functional rehabilitation and training required for the patients receiving this implant. **Most importantly the disease associated with this is not cataract, but rather age-related macular degeneration, and it should not be grouped with cataract procedures.**

Further the code descriptor was recently changed after further studies of the device showed that it could be successfully transplanted whether or not the patient still had their natural crystalline lens, and the same code is also now used for if the device is removed. The new descriptor states: Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis.

There are several codes included in the grouping that are done in rare circumstances and are unrelated to cataract removal procedures. The cataract surgery episode would be much more robust and resources more clearly identifiable if the episode only included the most common procedures related to cataract removal. There will also be a limited amount of patients to compare which will reduce the validity and reliability of the episodes. **The following codes should be removed: 66840, 66850, 66852, 66920, 66930, and 66940.** Similarly, for any discussion of secondary membranes after cataract that might be required, two codes were again listed that are rarely performed for this indication. **CPT 66820 and 66830 should be removed.**

- **The Academy believes a more accurate and workable grouper should be limited to 66982, 66983, 66984, and then 66821, a related service to treat common development of posterior capsule opacification.**

While the removal/ repositioning codes that were also included are clinically related, it should be recognized that there are clear clinical indications for either adding a second intraocular lens or exchanging a lens for patients. These services are rarely reported and will present similar problems with validity and comparison.

b. 120-Day Episode is not Appropriate for a Surgical Episode

Extending the episode length beyond that of the global surgical period will increase the likelihood of capturing services that are unrelated to the surgical procedure. This is especially true if CMS does not appropriately account for modifiers associated with diagnostic testing and evaluation and management services that would follow from the typical 90-day global period associated with all of these codes currently.

Another concern related to ophthalmology is laterality and the correct matching of RT/LT modifiers and/or the appropriate diagnoses codes. Similar to a Method A Episode, a surgical Method B Episode should be 90 days.

We also have concerns that diagnoses from unrelated initial procedures can be carried over on to claims. For instance, many times EHRs and or practices mistakenly carry over past diagnosis codes. In other cases, to avoid massive audits by MA plans related to a practice's diabetic patients, the diabetic diagnosis is often listed even when not the reason for the day's encounter. Cataract could also still be listed - when the patient has a cataract in the other eye. The ICD-10 code should clarify that it will be important to ensure that any diagnosis code of pseudophakia for post cataract patients are excluded.

IV. MIPS Clinical Practice Improvement Performance Category

The Academy appreciates CMS' efforts to design the new clinical practice improvement activity category in a way that is simple, meaningful to consumers and not overly burdensome to MIPS participants. We are pleased that CMS is proposing to allow ECs to submit their CPIA performance data through multiple reporting mechanisms, including attestation, qualified registry, QCDR, and EHR. **Also, we are particularly supportive of CMS' proposed yes/no attestation-approach for reporting CPIA data.**

CMS is proposing to require physicians to make a simple attestation to CMS or to a third party entity such as a clinical data registry that they have completed an activity considered by CMS as a clinical practice improvement activity. CMS says it plans to provide details on how this attestation must be submitted to CMS by providers and third party reporting entities, and we recommend that CMS allow a simple check the box type of attestation and submission for each activity. This would reduce reporting burden on providers and for third party entities such as registries. However, if CMS plans to conduct audits to validate providers' attestations, **we ask that CMS provide guidance on how they will audit and validate attestations. We also ask that CMS implement an appropriate channel for providers to appeal if a negative audit finding is brought forward.**

A. Activity Weights

In the rule, CMS proposes a list of 90 clinical practice improvement activities (CPIAs). Of these, CMS proposes to weight some activities as high, worth 20 points, and some as medium, worth 10 points. However, the Academy is concerned that there are too few activities weighted as high, **only 11 of these. As a result, many providers and practices will be required to report on six medium weighted activities. We believe that six is too high of a bar** given that this would be the first year for a brand new reporting category and a relatively low weight in overall CPS for the amount of effort. Instead, the Academy suggests that CMS reweight many of the medium activities as high, so that more CPIAs are worth 20 points, making it less burdensome and more meaningful for providers to achieve the full 60 points.

CMS explains that activities that align with national priorities and programs are weighted as high. However, the Academy notes that many activities related to participation in a clinical data registry are weighted as medium. **We recommend that CMS reweight all activities related to participation in a clinical data registry as high, as registries support the national goals of improved quality, better outcomes and lower costs. Further, MACRA called for the Secretary to encourage the use of registries in implementing MIPS, and assigning a higher point value to these activities would better fulfill this statutory obligation.**

B. Activities

We ask CMS to provide additional details and clarification on each of the activities. For example, CMS specifically uses the term "QCDR" in many of the activities. However, we note that many registries, including the Academy's IRIS Registry, have designations as a CEHRT, QCDR and qualified registry. If the provider is using a registry's CEHRT or qualified registry reporting option for the quality reporting category, CMS should clarify that he or she would

not be precluded from attesting to CPIAs that specifically call for participation in a “QCDR”. **Instead, we suggest that CMS clarify that these activities include participation in a specialty-led clinical data registry.**

The Academy also asks CMS provide clarification on what is required of providers to earn credit for each of the activities, and to provide details on what type of documentation would be required in the case of an audit. For example, one CPIA calls for expanded practice hours and 24/7 access to the medical record. The Academy believes that having a weekend and evening on call service would be sufficient to meet this activity. **However, we ask that CMS clarify this and provide details on all activities so that we can appropriately educate our members.**

V. MIPS Advancing Care Information Category

A. Clinical Quality Measure Reporting

The Academy strongly supports the removal of the CQM requirement for ACI. Under current reporting programs, providers must comply with quality reporting requirements for both Meaningful Use and PQRS, and the two programs are not fully aligned. The Academy applauds CMS’ efforts to align these programs under MIPS by removing the separate CQM requirement for ACI. We believe this will help to reduce burdens for physicians. We note, however, that CMS states in the rule that the CQM requirement is removed from ACI when the EC submits CQMs for the quality performance category using data captured in CEHRT. However, the rule implies that the CQM requirement is removed entirely from the ACI category for all providers. **The Academy asks for clarification, and urges CMS to remove the duplicative CQM requirement for all providers, regardless of their reporting mechanism for the quality reporting category.**

B. Group Reporting

The Academy supports the proposal to allow groups to report ACI data at the group level, rather than requiring providers to report at the NPI level, as is now required for Meaningful Use. We believe this option may help many practices to do well in MIPS by aggregating data across the practice, rather than evaluating each provider within the practice individually. Allowing the practices to aggregate their data to meet the base and performance requirements may enable more providers to earn points for this category with less burden.

C. ACI Data Submission

While the Academy appreciates CMS' proposal to allow third party entities such as clinical data registries and EHR vendors to submit ACI data rather than requiring all providers to attest to their ACI data, we note that this is a new concept, and no third party entities currently have this ability. It will take time and resources for these entities to build out this functionality, and not all eligible entities will have this capability initially.

In addition to time and resource constraints, we also have concerns with EHR vendors blocking the exchange of this data with registries. Currently, the Academy's IRIS Registry can report CQM data to CMS for PQRS and Meaningful Use, but some vendors block the exchange of this data with the registry, despite the physicians' desire to participate in the registry. To prevent this from happening with ACI data, we ask CMS to require vendors to exchange this data when requested by the physician with other third party entities, including registries.

D. Reporting Period

The Academy opposes CMS' proposal to require a full calendar year reporting for ACI. Especially as MIPS is first implemented and as Stage 3 is phased in during the 2018 performance year, a shorter reporting period is necessary to ensure providers are able to successfully make the transition to MIPS, upgrade their EHR technology to the 2015 edition, and meet the new Stage 3 measures by 2018. Complying with a full year reporting period for Meaningful Use or ACI is very difficult for the majority of providers. There a number of factors outside of a provider's control that make full-year compliance very difficult to achieve. Some examples include: switching EHRs, system glitches, updates and downtime, and office relocations. The Academy strongly encourages CMS to adopt a 90-day reporting period for the ACI category permanently, or at least in the first two years of MIPS to allow for a successful transition.

E. Registry Pathway to ACI Credit

Specialized registries are being implemented across many physician specialty societies, and they are being embraced by clinicians. For example, the Academy's IRIS Registry which launched in April 2014 now has over 13,500 participating physicians. Over 11,000 of these have electronically integrated their electronic health record systems with the registry. Over 90 percent of ophthalmologists that have successfully attested in the EHR Incentive Programs are participating in IRIS Registry. These physicians, using more than 40 different EHR systems, have electronically integrated with the registry to improve quality and patient outcomes. CMS should leverage this physician enthusiasm for clinical data registries and EHR adoption to improve performance and participation in the ACI category and MIPS.

IRIS Registry uses EHRs to collect and analyze the important data relevant to ophthalmology to provide physicians with on demand national and inter-practice benchmark reports on their performance related to clinical care and patient outcomes. The reports validate the quality of care ophthalmologists provide, pinpoint opportunities for improvement, and support population management. The IRIS Registry can also collect necessary data, calculate and report on clinical quality measures to CMS. Physicians using their EHR to participate in an electronic clinical data registry, such as IRIS Registry, for quality improvement purposes truly are “meaningfully using” CEHRT and “advancing care information”, and should receive full credit for ACI under MIPS.

Participation in an EHR-based national specialized registry would reduce reporting burdens for physicians, increase EHR use and ACI performance, and improve quality and outcomes. We strongly encourage CMS to recognize that a one-size-fits-all program does not meet the needs of all providers and patients, and we further encourage CMS to create an alternative pathway to success by providing full ACI credit to physicians participating in a national specialized registry using an EHR. As an alternative to providing full ACI credit, CMS could provide the 50 base score points to physicians who participate in a specialized registry under the ACI category for MIPS.

F. Base Score

The Academy applauds CMS for proposing to remove the minimum patient percent thresholds currently required for Meaningful Use. The Academy has long opposed these thresholds which were arbitrary, supported by insufficient evidence, and oftentimes very challenging for providers to meet. The Academy believes that requiring providers to report each measure on just one patient is more attainable. Under CMS’ proposal, a provider is unable to earn any credit under ACI unless they report each measure for one patient and to answer “yes” to measures that require a yes/no response.

However, we are concerned that such a proposal carries on the flawed “all or nothing” design of Meaningful Use. The ACI or Meaningful Use requirements are not relevant to all providers, and CMS should not implement a scoring methodology which requires all providers to report all measures, even if for just one patient, as it is not realistic for all providers. Instead, CMS should allow providers to earn partial credit based on their performance for the measures reported.

Under the proposal, a provider achieving 100 percent performance on all ACI measures included in the base score except for one would receive a zero for the entire ACI category, despite their excellent work on the all of the other requirements. There are many

reasons why a provider might not report on one requirement, including that it may be overlooked because MIPS and ACI are so new, high technology costs associated with complying with the requirement, or lack of relevancy to his or her patient population. **The Academy strongly encourages CMS to remove the all or nothing structure of the base score, and allow providers to earn partial credit based on the measures they report.**

G. Performance Score

The Academy appreciates the flexibility proposed for the performance score under the ACI category. Providers have the opportunity to earn more than the maximum number of points, which provides room to focus on measures that are most relevant to the practice. While we appreciate that CMS has proposed to remove the arbitrary patient reporting thresholds that exist today under Meaningful Use, we note that the performance score methodology requires a provider to report on 100 percent of patients for each measure in order to earn the full 10 points eligible for each measure. **We are concerned that this may set a higher bar than what is in place today under Meaningful Use.**

Our comments on the measures that will be used for evaluation of providers under MIPS for the performance score are outlined below:

1. Modified Stage 2

For purposes of the Base Score, CMS is proposing that providers can opt to report on Modified Stage 2 measures in 2017, which the Academy applauds. However, CMS includes Stage 3 measures in the performance score. While many of these measures cross both Stage 2 and Stage 3, there are several Stage 3 measures which are not included in Modified Stage 2, including the Patient-Generated Health Data measure, the API requirement under the View, Download Transmit measure, and the Health Information Exchange Request/Accept Patient Care Record measure. As a result, there would be fewer points that providers in Modified Stage 2 could earn compared to those in Stage 3, putting them at a disadvantage. Therefore, we ask CMS to even the playing field and to modify the performance score methodology so that providers in Modified Stage 2 are able to earn the same number of points as those in Stage 3.

The Academy strongly supports the removal of the Clinical Decision Support and Computerized Provider Order Entry objectives beginning in 2017 for all providers in MIPS. The value of CDS is determined by its relevance to a patient's care, and to date, there have been limited CDS activities relevant to ophthalmic care. Therefore, we support

the removal of the CDS objective from the ACI category under MIPS for all providers beginning in 2017.

The Academy also supports the removal of the CPOE objective from the ACI category under MIPS for all providers beginning in 2017, as it would greatly reduce burden on providers.

Since the creation of Stage 2, the diagnostic imaging measure under the CPOE objective has ignored the workflows of ophthalmologists because it includes the ordering of low-risk in office imaging. As such, this measure has created immense administrative burden on ophthalmologists. Ophthalmologists perform a very high volume of in-office imaging tests that present no risk to patients. For example, consider Optical Coherence Tomography "OCT" which is also called "SCODI" for Scanning Computerized Ophthalmic Diagnostic Imaging. This is a non-invasive imaging test that uses light waves to take cross-section pictures of the eye. To examine the optic nerve, this test (CPT 92133) was ordered 2.26 million times in 2013 for traditional Medicare patients (exclusive of Medicare Advantage), and to examine the retina, this test (CPT 92134), was done nearly 5 million times in 2013 for Medicare Part B. These high-volume tests are always performed in the ophthalmologist's office, and there is no risk to the patient, but they were included in the CPOE requirement for Meaningful Use.

Further, for all measures under the CPOE objective, CMS has required orders to be entered into the EHR by certified medical assistants or equivalent, which presents significant workflow and financial challenges because many ophthalmology offices do not have formally certified technicians or assistants. This has created an even greater challenge for ophthalmologists because of the inclusion of low-risk in office imaging orders. Physicians have to spend significant amounts of money to have their staff certified simply to meet this one requirement. The removal of the CPOE objective would eliminate the need for practices to obtain formal certification for staff that enters electronic medication, laboratory or radiology orders into the EHR. Therefore, Academy supports the removal of the CPOE objective from the ACI category for all providers under MIPS beginning in 2017.

The Academy strongly supports the specialized registry measure under the Stage 2 Public Health objective. However, we seek clarification and encourage that the specialized registry measure would continue to be a *required* measure under Stage 2 in 2017, rather than being

optional. This measure provides physicians participating in a clinical data registry such as IRIS Registry with credit for the public health objective. If required, this measure would also encourage physician participation in an important quality improvement tool. We support the specialized registry requirement, and believe it provides incentive for specialty providers to enroll in their specialty's clinical data registry to improve quality and outcomes. However, the other measures under the public health objective have little relevancy to ophthalmology. Ophthalmologists do not administer immunizations, and do not directly diagnose or treat conditions associated with the syndromic surveillance measure. **The Academy supports CMS' proposal to exclude providers who do not administer immunizations from the immunization registry measure, but a similar exclusion should exist for the syndromic surveillance measure for physicians who do not directly or rarely diagnose or treat conditions related to syndromic surveillance.**

Finally, the Academy opposes the Patient Electronic Access objective, which includes measures that evaluate a provider based on the actions of a patient or another healthcare provider. It is impossible for a physician to force his or her patients or another healthcare provider to take any action. While the physician can encourage patients to take certain actions, there is no reasonable way that physicians can guarantee that patients take those actions. Therefore, we encourage CMS to remove these measures from the ACl category for MIPS.

2. Stage 3

The Academy is concerned that the requirements for Stage 3 build upon the onerous Stage 2 requirements, prior to the recent modifications. The Academy notes that only a very small percent of eligible professionals have been successful in Stage 2, necessitating CMS' modifications to Stage 2 last year. The Academy continues to have concerns with the requirements themselves, as there is little to no evidence demonstrating that they support the achievement of improved quality, patient outcomes, costs or interoperability. In fact, most physicians believe that the Meaningful Use requirements are a hindrance to delivering excellent patient care. In membership surveys, Academy members broadly express their concerns, not only regarding their inability to achieve the strict Meaningful Use requirements, but with the overall effectiveness of the program, and the distraction from patient care the program often creates. Many of these physicians appreciate their EHR system, but find the Meaningful Use requirements to have little value with too much administrative burden. In addition,

the Government Accountability Office recently reported that the Meaningful Use program is a barrier to interoperability.

The Academy is strongly opposed to the measures included under the Coordination of Care Through Patient Engagement and Health Information Exchange objectives, and urges CMS to remove them from the program. These requirements which hold a provider accountable for the action taken by a patient or another healthcare provider are inherently flawed because they measure physicians against criteria over which they have absolutely no control.

Physicians have no control over another physician's decision to use an electronic health record, as required for the Health Information Exchange objective. **A physician should not be held accountable for a measure which requires the action of another provider.** For example, for the Health Information Exchange objective request / accept patient care record measure requires another healthcare provider to send a summary of care document in order for the receiving physician to earn credit for the measure. The Academy asks CMS to remove these measures because physicians cannot control the ability of another provider to electronically send or receive summary of care information.

Similarly, a physician cannot force his or her patient to electronically view, download or transmit their health information to a third party, or electronically access their health information through the use of an API; a physician also cannot force a patient to send non-clinical data to the physician's EHR. While the physician can encourage patients to take certain actions, there is no reasonable way that physicians can be guaranteed that patients take them. The Academy recently solicited feedback from Academy members on their experience with EHRs and the Meaningful Use program, and overwhelmingly, Academy members cited the patient action measures as the most complex and difficult to meet. Ophthalmologists' patients are typically elderly and not tech savvy, and often have vision problems making electronic access of health information impossible. Other Academy members report that most of their patients would prefer to spend a few extra minutes with the physician to have their health information explained to them, face-to-face, rather than viewing it online or through an API. While efforts to better engage patients should be applauded, we do not think this is the right way to achieve that end. **We strongly encourage CMS to remove these measures entirely from the program.**

The API requirement also presents a number of technical issues because the API standard is not fully specified or ready for use. We encourage CMS to refrain from requiring use of an under-developed standard. In addition, we have significant privacy and security concerns with the API requirement, as the measure would require a physician to share protected patient health information with any app of the patient's choice, yet there would be no way for the provider to verify the security of apps with which patients may ask to have their information shared.

The secure messaging measure provides little value but instead creates an administrative hoop for physicians to jump through in order to succeed in ACI - that is sending as many patients as possible a secure message, despite the relevance or necessity of that message, in order to score high points for MIPS. This measure should be removed from the program. Instead, physicians should only be required to have this functionality available through their EHR, providing all patients with the options of sending a secure message to the physician if they choose to do so.

We are opposed to the patient-generated health data requirement. There are very few if any devices relevant to eye care that a patient could use to generate data to share with an ophthalmologist. We also have physician liability concerns related to potential issues that may stem from the inclusion of patient-generated data in the medical record, and also are concerned about the quality and relevancy of non-clinical patient generated data. Further research in this area would be anticipated to improve the product and possibly make it suitable in the future. **We do not support this measure at this time and ask CMS to remove it from the program.**

The Academy is pleased that providers reporting to a specialized registry such as the Academy's IRIS Registry can earn a bonus point for ACI, but we do not believe that one bonus point out of a total possible 130 points for the ACI category would provide any incentive to encourage providers to utilize clinical data registries. Instead, CMS should give full ACI credit to providers electronically participating in a specialty registry. As an alternative to full credit, CMS could give full base score points to these providers. The Academy reiterates that one bonus point is not sufficient credit for electronic participation in a specialized clinical data registry. The Academy supports CMS' proposal to make the other public health measures, which have little relevancy to ophthalmology, optional for the ACI category under MIPS in Stage 3.

H. Health Information Exchange and Prevention of Data Blocking

Under the ACI category, CMS proposes to require ECs to demonstrate that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability or health information exchange. However, no similar demonstration is required of EHR vendors. **The Academy strongly encourages CMS require vendors to also attest that they did not take action to limit or restrict interoperability or information exchange.**

We believe that interoperability is essential to achieving higher quality and better care. However, some electronic health record vendors are intentionally blocking the exchange of information, including not adopting the standards needed to accomplish information exchange in a timely fashion, or charging unreasonable fees to exchange clinical data – all hindering efforts to electronically exchange information in order to improve patient outcomes. The Academy operates the IRIS Registry, the world’s largest eye disease and condition registry with over 13,500 participating physicians, and more than 88 million records from 23 million unique patients—growing daily. The registry was developed by the Academy to lead significant innovations and improvements to medical and surgical eye care in the U.S., prevent vision loss, and support government initiatives to increase value for patients in the U.S. health care system. Since the launch of IRIS Registry in 2014, many other specialty societies have followed in launching similar registries aimed at improving quality and patient outcomes.

Clinical data registries are being embraced by practicing physicians who want to improve their quality and patient outcomes, and streamline their quality reporting to CMS. Given the widespread adoption of health information technology, clinical data registries can harness and populate the data from various EHRs to effectively measure quality and performance, and track patient outcomes overtime. However, information blocking is a real obstacle to the benefits of EHR technology when EHR vendors refuse to share electronic health information, or create financial or other barriers precluding such data from being shared with other systems, including clinical data registries. Physicians are prevented from automated electronic participation in important tools like clinical data registries. While physicians may want to share their data to participate in a clinical data registry, there is little they can do if an EHR vendor prohibits or charges exorbitant fees for participation. **Requiring vendors to provide an attestation that they did not take action to restrict data exchange with other entities including clinical data registries would begin to address this issue.**

VI. Qualified Clinical Data Registry Self-Nomination Process

In the rule, CMS proposes a number of changes to the QCDR self-nomination process. The Academy understands CMS' rationale for moving up the timing of self-nomination period, but we have concerns that this may conflict with the rulemaking cycle. Moreover, CMS is proposing that QCDRs execute their data validation plan by May 31, rather than June 30. The Academy has some concerns with this date because our registry staff are fully dedicated to data submission in the first three months of the year. They are not able to focus on data validation until after quality submissions are completed in March.

This timeframe will stretch resources and reduce the time that can be dedicated to this even further.

CMS is also proposing to increase the number of times QCDRs must provide feedback to its participants from four times annually to six. This requirement can currently be met when providers have the ability to generate reports on demand. However, this option is not explicitly mentioned in the rule. We ask CMS to clarify that the ability to generate reports on demand would satisfy the annual feedback requirements.

CMS is proposing that QCDRs' participation in ongoing support calls and attended an in-person kickoff meeting at CMS headquarters in Maryland. The Academy is concerned with the in-person meeting requirement, as our registry staff is based out of San Francisco, and it may not be feasible to attend the in person meeting in Maryland.

CMS outlines a plan to reduce QCDR data inaccuracies including TIN/NPI mismatches, formatting issues, calculation errors and data audit discrepancies. CMS proposes that a QCDR with more than 3 percent of total submissions affected by errors may result in the QCDR being notated as having 'low data quality' and would place the QCDR on probation. CMS also proposes that a QCDR with more than 5 percent of total submissions affected by errors would lead to disqualification from participating in the subsequent performance year. **We strongly agree with the need for accurate submissions; however, these thresholds seem too stringent, particularly considering this will be the first year of MIPS. Instead, we recommend that CMS increase the thresholds at minimum to 5 and 8 percent, respectively.**

VII. Public Reporting/Physician Compare

The Academy supports transparency and appreciates CMS' efforts to provide meaningful information to consumers to enable them to make better informed healthcare decisions. We have longstanding concerns, however, about the accuracy and clarity of new data to be published on Physician Compare. In addition to the accuracy, validity and reliability of the publicly reported data, the Academy has concerns about the unintended consequences that the publication of new performance data can have on consumers and providers when published data are not fully explained and understood by consumers.

This is especially true in a system where having winners and losers mandated by a budget neutral scoring system could mean that scores have more to do with arbitrary thresholds than with true quality of care. We are very concerned with the public's ability to be educated about and understand the scoring system. Therefore, the Academy supports further testing to ensure that consumers understand the MIPS CPS, the quality measures under consideration for public reporting as well as their relevance to the healthcare decision making process prior to publicly reporting new information. This is a very complicated program and distilling it to a single or a few publicly reported scores would likely be difficult to explain. In addition, the magnitude of differences on the CPS have yet to be studied for their predictive value about physician differences.

A. Composite Score, Performance Categories, and Aggregate Information

While supporting transparency to improve patient care and physician performance, the Academy will continue to advocate against the expansion of such public performance reporting until the data can be verified as accurate and valid and presented in a way that is useful to consumers. For instance, CMS does not account for demographic or socioeconomic status in its performance scores. Physicians who treat higher risk patients may appear to have a lower performance on outcome measures than other physicians. The Academy asks the agency not to move forward with expanding public reporting of quality data until the information can be verified as correct and valid, and clearly understood by consumers, especially given how relatively new some of the data will be. Moreover, we have concerns regarding potential legal ramifications physicians could face if performance scores are posted. Should a physician be on trial for malpractice, it would be very easy for an attorney to pull a low performance score for a certain measure and use it against the physician. Our concern is compounded by the public reporting of data that is not sufficiently risk adjusted, valid, or reliable. The Academy supports data used to help consumers make informed healthcare decisions, and we agree with CMS that if a consumer does not understand or properly interpret a quality measure, misunderstanding what the quality score represents, the consumer cannot use this information to make an informed decision.

CMS seeks comment on the advisability and technical feasibility of including data voluntarily reported by EPs and groups that are not subject to MIPS payment adjustments, such as those practicing through RHC, FQHCs, etc., on Physician Compare. The Academy is in support of data that assists consumers into making sound healthcare decisions; however, we echo CMS' thoughts that too much information can be confusing to patients and lead to poor decision making.

Therefore, we believe CMS should only post what the agency is legally mandated to.

The Academy continues to support CMS' proposal to give providers a preview period to view their measures as they will appear on Physician Compare prior to the measures being published. However, we are concerned that the proposed 30-day period is too short. We encourage CMS to allow for a longer review period so that there is adequate time to explain the score, and for providers to react. It is critically important that physician groups have the opportunity to review quality data for accuracy prior to publication and have an opportunity to correct discrepancies. In addition, we support publicly reporting benchmarks along with performance data in order to help to provide a point of reference for consumers to make more informed choices.

B. Quality

CMS states that it will publish all performance rates on quality measures on a downloadable database. Previously CMS stated that it would publish performance rates on quality measures that were statistically valid and reliable, and deemed to be statistically comparable. CMS defined this as meaning the measures evaluate the same phenomena in the same way regardless of the mechanism through which they were collected (i.e. what reporting modality was used). The Academy supported this concept, as we know that the reporting modality used by a provider significantly impacts performance rates. We hope that CMS will continue with its previous proposal. However, we have questions around the methodology used by CMS to determine if a measure's performance rates meet these criteria. Transparency is very important in making sure this is done appropriately. More information is required about how CMS makes this determination.

C. Resource Use

The Academy is strongly opposed to the flawed cost and resource use measures utilized under the current Value-Based Modifier Program, and is opposed to any carryover of flawed, existing methodologies from current policies. We recognize the importance of measuring cost and resource use, but we strongly urge CMS to identify alternative, and more accurate and appropriate measures to evaluate cost and resource use under MIPS.

Under the Total Cost of Care measure, ophthalmologists are held accountable for the cost of care provided to their attributed beneficiaries by other providers. This includes costs that are completely unrelated to ophthalmology and eye diseases because the measure evaluates all Medicare Part A and B costs for attributed patients. This information can be misleading to

consumers as it will appear that certain physicians are high-cost. Further, the Medicare Spending Per Beneficiary Measure analyzes costs associated with inpatient admissions; yet, ophthalmologists rarely admit patients to a hospital for eye care. Therefore, this measure too is an inappropriate evaluation of the cost and resource utilization for ophthalmologists.

These measures are unfair to a broad range of providers, including ophthalmologists, are inaccurate and misleading, and should not be utilized under MIPS. We strongly agree with CMS that resource use data do not resonate with consumers and can lead to significant misinterpretation and misunderstanding. We believe posting any information related to resource use on individual EP pages would be highly misleading to consumers, who don't understand how the program works. It would also be highly unfair to physicians, because most of the factors used to determine physicians' value are completely out of their control.

D. Utilization Data

Payment records can potentially mislead patients as the data does not indicate whether a payment was made to a single provider or to multiple providers out of a single office. Many physician practices use one provider's Unique Physician Identification Number for billing purposes making it appear as though one physician was highly reimbursed. The data also does not indicate what portion of a payment represents reimbursement to physicians, especially those who make small profits from treating patients with expensive drugs or treatments. When an ophthalmologist administers macular-degeneration treatments, the cost of the drug minimizes what the physician is able to collect. This can lead consumers to believe that certain providers are high-cost and may even deter patients from seeking care they need. **The Academy believes if CMS deems the data inappropriate for EP profiles as it is not useful to the average Medicare consumer, then it should not be accessible to the public in a raw data file.** This opens the door for major corporations to manipulate and exploit the data and use it to their advantage.

The Academy would like to reiterate that the ACA established Physician Compare and intended for it to be a website providing information on physician quality performance; therefore, all data not quality related should be excluded unless there is additional statutory authority and scientific support for the validity of such data.

E. APM Data

The Academy is in support of the idea of using APM data to meet MIPS reporting requirements and agrees that approaches that increase efficiency and avoid duplication should be favored.

However, we believe that requiring data submission linked to an APM as mandatory rather than as an option may force some clinicians into APM-based reporting against their will and against their best interests. Use of APM data to meet MIPS requirements should be an encouraged option, but not mandatory.

CMS states that it will only publish performance category measures that meet the public reporting standards on its website through a downloadable database. The Academy questions how CMS will determine whether or not certain measures fall in line with public reporting standards. The Academy also questions what criteria CMS will use to choose a subset of measures to be placed directly onto the website. In addition to this, CMS states that it will publish performance scores of participants in APMs. The Academy also asks CMS to clarify if it will publish a total performance score or only performance scores on measures that it publishes on its website.

We appreciate the opportunity to comment on the CMS proposed rule regarding the Merit Based Incentive Payment System under the Quality Payment Program. Please see the attached Appendix A for a high level summary of our recommendations, concerns and comments. If you have questions or need any additional information, please contact Ms. Cherie McNett, Health Policy Director at cmcnett@aaodc.org or via phone at 202-737-6662. Again, the Academy would like to thank you for providing us with the opportunity to comment and to work with CMS. We look forward to ongoing engagement and stakeholder input.

Sincerely,



Michael X. Repka, M.D.
AAO Medical Director for Government Affairs

Appendix A: American Academy of Ophthalmology Top Line Recommendations, Concerns and Comments

MIPS Policies:

- The Academy encourages maintain an open and continuous dialogue with practicing clinicians and medical specialty societies to identify unintended consequences of this new program as early as possible.

MIPS Performance Period:

- While a delay would help preparation, the trade-offs for that would create inequities for ophthalmologists and many other specialties under the most significant portion of MIPS—Quality Reporting.
- If CMS does decide to implement a July start date for MIPS performance, there should continue to be a one-year performance period, and accommodations made that would minimize the negative impacts caused by a shortened performance period such as smaller sample size, bias or variable benchmarking for these important outcome measures.

Clinical Data Registries and MIPS:

- Strengthening and encouraging the development of clinical registry platforms should be one of CMS' major priorities, and ask CMS to take even more steps to incentivize physicians and recognized those who choose to participate in these entities.
- CMS should further encourage the use of QCDRs, including:
 - Reduce the reporting burden for QCDR participants under the quality performance category by lowering the data completeness standard from 90 percent of patients from all payers to 50 percent of Medicare patients, and by allowing QCDRs to report on measures groups.
 - Allow QCDR non-MIPS quality measures to earn electronic reporting and outcome measure bonus points.
 - Increase the weight of all CPIAs that involve participation in a clinical data registry or QCDR to "high", each worth 20 points.
 - Allow EHR-based MIPS participants using a specialty-led clinical data registry to qualify for full credit, or at least full-base score credit under the ACI category.

MIPS Identifier:

- The NPI/TIN combination has led to confusion and increased burden, especially among physicians practicing in more than one location.

MIPS Exclusions:

- The Academy appreciates CMS' proposal to exclude certain clinicians from MIPS and supports the categories for which exclusions are offered, but seeks clarification on how the MIPS exclusions for ECs would apply to groups that report at the TIN level.
- CMS should extend the exclusion for newly enrolled ECs an additional year so that sufficient time can be provided for these physicians to acclimate to their practices and begin participation in MIPS.
- The Academy recommends that CMS raise the low volume threshold to \$30,000, and exclude from MIPS physicians that exceed either the dollar or patient cap, and also asks for flexibility so that providers are not burdened by MIPS penalties when they slightly exceed the threshold.
- The Academy asks CMS to implement exceptions from penalties for providers who are unable to participate in MIPS due to a significant hardship.

Virtual Groups:

- Establishment of the virtual group reporting option for the 2017 performance period would go a long way to addressing concerns of many medical specialties that see no ability to adopt an APM in 2017 under the proposed rule.
- We encourage CMS to continue to work on the needed technology infrastructures so that virtual groups may be implemented as soon as possible.

MIPS Reporting Mechanisms:

- The Academy appreciates that CMS is proposing a broad number of mechanisms that providers can choose from for submitting data to meet the requirements of the various components of MIPS.
- Third party entities such as registries should have the option, but not be required to have the capability to submit data for all MIPS applicable performance categories, especially in the first year of the program.

- CMS should allow registries to declare later in the performance year if they plan to support data submission for each of the MIPS categories.

Small Practice Technical Assistance Funding:

- We request that CMS reserve some of the technical assistance funding for specialty societies such as the Academy so that we can more effectively provide specialty- specific guidance to our members in small practices and rural settings.

MIPS Quality Performance Category:

- We are pleased with the flexibility introduced by CMS in allowing physicians to get partial credit for the measures that are reported.
- The Academy strongly encourages CMS to maintain measures groups as a quality reporting option under MIPS, including the cataracts and diabetic retinopathy measures groups, and to allow QCDRs to report on measures groups for their participating physicians. Measure groups are important to quality measurement, as they are designed as composite measures to provide an overall picture of patient care for a particular key medical condition or set of services.
- Small practices and solo practitioners would be negatively impacted if CMS finalizes its proposal to eliminate measures groups.
- The Academy urges CMS to reduce the minimum number of measures required for initial reporting from six to three.
- We ask that relevant stakeholders have the opportunity to learn details about and comment on the future MAV process prior to it being finalized.
- The Academy is opposed to CMS' proposal to require physicians using all quality reporting mechanisms except for claims reporting to report on patients from all payers, rather than only Medicare patients.
- The Academy opposes CMS proposal to increase the number of patients a provider or group must report on from 50 percent to 80 percent for claims reporters, and to 90 percent for qualified registry and QCDR reporters. These high thresholds are unreasonable and will prevent many providers who make good faith efforts to succeed from doing well under MIPS. We ask CMS

to significantly lower the proposed data completeness standards to a maximum of 50 percent.

- We ask CMS require or provide extra points when specialists practicing in groups utilizing the GPRO Web Interface option participate in their specialty's clinical data registry when applicable.
- The Academy asks that CMS exclude measures 303 and 304 from the MAV process, and permit providers to report them on a sampling of patients, such as 20 patients.
- We request that CMS exclude ophthalmologists from the claims-based population quality measures and reweight the reported measures so that no points would be lost.
- The Academy is pleased that CMS did not propose to remove measures which it considers to be "topped out."
- The Academy opposes CMS proposed scoring method for topped out measures, that would disadvantage many of these small practices that have fewer measure options and hurt providers delivering high quality care.
- We ask CMS to clarify that it will provide these bonus points for QCDR measures that are not included in the MIPS measure set but that are outcome, patient experience or other high priority measures, and QCDR measures that are not in the MIPS measure set but that are submitted with end-to-end electronic reporting, including QCDR measures reported on XML.
- The Academy supports the higher 10 percent cap on bonus points, as it would be more effective at encouraging the use of outcome measures and electronic reporting.

MIPS Resource Use Category:

- The statute says that Resource Use should carry a maximum weight up to 10 percent for the first year. Congress intended to provide flexibility to the Secretary in the weighting of the performance category, and we believe that a weight of no more than five percent is more appropriate. CMS should realign the other portion to either the Clinical Practice Improvement or Advancing Care Information categories or distribute it to both.
- Additionally, until CMS has overcome the serious flaws we have pointed to in the Method B cataract grouper, it should not be utilized.

- CMS should indicate whether the revised changes to the HCCs when finalized in February 2017 will be used for risk adjustment for the MIPS Resource Use Category.
- The Academy encourages a process whereby major national medical organizations such as the Academy would work together with CMS and other stakeholders to create resource use measures that are risk adjusted, appropriately aligned with available quality measures, and fairly attributed.
- The Academy strongly disagrees with the proposal to lower the minimum patient threshold for some resource use measures, as the higher numbers ensure greater statistical reliability for the measure and offset the impact of outliers.
- We do not support the Total Per Capita Costs measure because the risk adjustment methodology continues to be problematic, attribution strategies are unreliable, and the measure does not appear actionable by smaller groups.
- The Academy has plans to develop new appropriate use measures addressing two Choosing Wisely guidelines, which will be more appropriate measures of resource use for ophthalmologists and should be included in MIPS in future years.
- The Academy does not support the Mean Spending Per Medicare Beneficiary (MSPB) measure and is concerned that it is not readily actionable and it fails to link to measures of quality of care.
- The Academy previously submitted to CMS its substantial concerns in February about the Method B Resource Use Measure for Cataract including pointing to incorrect trigger codes that have no diagnosis of cataract associated with them. From our review of Method B as well as the other episode groupers now released by CMS, it is clear that no practicing ophthalmologist reviewed or was involved in the final products.
- The Cataract Measures Group should be aligned with the Method B Resource Use Measure for Cataract. This is another reason why this and other measures groups should be retained.
- There are significant problems regarding the codes that would trigger the cataract episode grouper.
- The Academy believes a more accurate and workable grouper should be limited to 66982, 66983, 66984, and then 66821 which is a related service to treat common development of posterior capsule opacification.

Clinical Practice Improvement:

- The Academy supports CMS' proposed yes/no attestation-approach for reporting CPIA data; however, we ask that CMS provide guidance on how they will audit and validate attestations.
- We recommend that CMS reweight all activities related to participation in a clinical data registry as high.

Advancing Care Information:

- We support the removal of the duplicative CQM requirement for all providers, regardless of their reporting mechanism for the quality reporting category.
- The Academy supports the proposal to allow groups to report ACI data at the group level.
- The Academy opposes CMS' proposal to require a full calendar year reporting for ACI.
- CMS should create an alternative pathway to success by providing full ACI credit or the full 50-point base score to physicians participating in a national specialized registry using an EHR.
- The Academy strongly encourages CMS to remove the all or nothing structure of the base score, and allow providers to earn partial credit based on the measures they report.
- The scoring methodology for the ACI performance score that this may set a higher bar than what is in place today under Meaningful Use.
- We ask CMS to even the playing field and modify the performance score methodology so that providers in Modified Stage 2 are able to earn the same number of points as those in Stage 3.
- The Academy strongly supports the removal of the Clinical Decision Support and Computerized Provider Order Entry objectives beginning in 2017 for all providers in MIPS.
- The Academy is strongly opposed to the measures included under the Coordination of Care Through Patient Engagement, Patient Electronic Access and Health Information Exchange objectives, and urges CMS to remove them from the program.
- The Academy is pleased that providers reporting to a specialized registry such as the Academy's IRIS Registry can earn a bonus point for ACI, but we do not believe that one bonus point out of a total possible 130 points for the ACI category would provide any incentive to encourage providers to utilize clinical data

registries. Instead, CMS should give full ACI credit to providers electronically participating in a specialty registry. As an alternative to full credit, CMS could give full base score points to these providers.

- The Academy strongly encourages CMS require vendors to also attest that they did not take action to limit or restrict interoperability or information exchange to address the issue of data blocking.

QCDR Proposals:

- While we agree with the need for accurate submissions, we ask CMS to increase the proposed error rate thresholds.

Public Reporting:

- The Academy has concerns about the unintended consequences that the publication of new performance data can have on consumers and providers when published data are not fully explained and understood by consumers.
- We encourage further testing to ensure that consumers understand the MIPS CPS, the quality measures under consideration for public reporting as well as their relevance to the healthcare decision making process prior to publicly reporting new information.
- While we support CMS' proposal to give providers a preview period to view their measures as they will appear on Physician Compare prior to the measures being published, we are concerned that the proposed 30-day period is too short.
- Data deemed inappropriate for EP profiles as it is not useful to the average Medicare consumer, should not be accessible to the public in a raw data file.
- The Academy also asks CMS to clarify if it will publish a total performance score or only performance scores on measures that it publishes on its website.