



AMERICAN ACADEMY™  
OF OPHTHALMOLOGY

20 F Street NW  
Suite 400  
Washington DC  
20001-6701

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P.O. Box 7424  
San Francisco, CA  
94120-7424

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T: +1 202.737.6662  
[www.aao.org](http://www.aao.org)

June 27, 2016

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 comments on the CMS proposed rule regarding the Alternative Payment Model (APM) Incentive Program under the Quality Payment Program. 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 high 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.

With Alternative Payment Models (APMs) being the long range CMS goal for how providers are paid, it is difficult to see how surgical specialty care will fit into APMs based on our review of the proposal. Through these comments we will provide our thoughts on provisions that could be improved to broaden APM options to encompass more physicians and include specialties like ophthalmology that serve a large Medicare population.

Access to real-time data as well as continuous feedback and reporting capabilities is paramount to APM success. Congress recognized in MACRA, the role the clinical data registries add to quality and value. **The Academy encourages CMS to work with specialties to examine the role that such registries can contribute to bring in more specialties as APMs.**

## **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 included 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® (Intelligent Research in Sight) Registry in 2015PQRS. 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 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 recognized this type of registry publicly and stated in this proposed rule that clinical data registries are providing significant contributions to a value-based healthcare environment. We see several 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 suggest that CMS take further steps to incentivize physicians and recognized those who choose to participate in these entities throughout the Quality Payment Program (QPP) including APMs.

## Recognition of Clinical Data Registries

The Medicare Access and CHIP Reauthorization Act of 2015 calls on the Secretary to encourage the use of registries in implementing MIPS. Congress intended that the use of registries and other forms of health information technology be used where applicable to facilitate reporting under the MIPS program. Congress also saw great potential in the role that registries could play in future development under the program. For instance, the potential for registries to act as feedback loops for providers seeking to better understand their performance and ways to improve it is immense. Powered by analytics and other tools, registries hold the potential to support a system of learning and improvement for those engaging with such platforms.

Congress also called on CMS to advance quality measurement and APM development using Medicare data. Such potential, if realized, can greatly increase provider confidence in the program and the Administration's effort to implement the law. However, in order for such a process to work, it is important that CMS recognize registry data as valid data sources for pre-testing purposes.

CMS endorsement of registry data as a viable means of satisfying requirements for further testing or adoption can be a key step in the process of supporting broad development of the quality measures and the APMs necessary to make the MIPS program and APM pathways viable. Recognition of such requirements should be included in its final rule. In doing so, we recommend that CMS solicit feedback from organizations that maintain and operate such registries. The Physician Clinical Registry Coalition of which the Academy is a member is one such organization and they would be an excellent resource for CMS as they seek to improve and enhance APMs.

## APMs for Specialty Care

The MACRA statute requires that APMs be authorized through the Centers for Medicare and Medicaid Innovation (CMMI), a shared savings program, or a demonstration required by federal law. As authorized under Section 1115A of the Social Security Act, CMMI models must improve the quality of care without increasing spending, reduce spending without reducing the quality of care or improve the quality of care and reduce spending. Congress intended that the APM pathway with annual updates be a viable option for medical providers of all types as it understood physician confidence in the new system was paramount to its long-term success. However, based on our review of the proposed rule, the Academy does not see a viable APM path for most specialists including ophthalmologists.

**The Academy encourages CMS in the final rule to provide more voluntary opportunities for specialists who are not primary care physicians to participate in MIPS APMs and Advanced APMs.** Based on the APMs listed in Table 32 that would currently qualify as MIPS or Advanced APMs, the only specialist physicians who would have access to an eligible APM are subsets of oncologists and nephrologists who have applied for and been approved to participate in the CMS oncology and ESRD models.

## Physician Technical Advisory Committee (PTAC)/Physician Focused Payment Model (PFPM) Criteria

The Academy urges CMS to provide a clear pathway for models recommended by PTAC to be implemented as APMs under MACRA. We commend the efforts of the PTAC to put in place a timely and predictable review process for stakeholder models, but remain very concerned that CMS is unwilling to do the same. Congress clearly foresaw MACRA providing for development of a robust array of PFPMs that could help improve care for patients with Medicare and other insurance. Many specialty societies that have been working to develop PFPM proposals are alarmed by comments from CMS officials. Indications are that proposals that will be recommended by the PTAC to the Secretary, will still need to go through a separate, potentially years-long CMS process before they could be implemented and qualify as APMs under MACRA.

The Academy recommends that the final rule establish a streamlined, straight forward pathway for PFPM proposals to be adopted as advanced APMs. **We do not support the CMS proposed language that precludes PFPMs that address a disease, condition or episode that is included in other payment models.** In order to find the best patient care to combat severe chronic diseases, multiple avenues should be offered. Diseases like glaucoma or age-related macular degeneration (AMD) are not one-size fit all conditions and options should be open to various ways in which to provide value-based treatments for Medicare patients.

The final criteria must be clear and not overly complicated in order to encourage organizations to devote the time and monetary resources to develop a payment model that would be meaningful for both patients as well as the physicians caring for them. **Finally, we encourage CMS and the PTAC to work collaboratively with medical societies and other organizations developing proposals, provide rapid feedback on drafts, and provide data up-front to help in modeling impacts of each proposal.**

### More APMs are Needed

CMS' stated goal of having 50 percent of Medicare payments from APMs by 2018 is unattainable unless and until the number and opportunities for all physicians to participate in APMs is expanded. CMS needs to develop a pathway and provide assistance to organizations that wish to develop and/or become participants in MACRA APMs. Further, the proposal does not provide a clear pathway to help MIPS APMs transition to Advanced APMs and we would encourage CMS to begin a process that would move MIPS APMs into the Advanced category. Those involved in the development of MACRA did not contemplate three separate categories for participation: MIPS, Advanced APMs, and MIPS APMs.

The appropriate role for MIPS APMs is as a transitional step to Advanced APMs, but we are uncertain what that transition would look like. Discussing the Advanced APM financial risk requirements, CMS comments in the NPRM that its proposal "reflects our belief that more and more APMs will meet this high bar over time." With just one percent of Medicare ACOs in Track 2 and

four percent in Track 3, many have questioned the validity of CMS' belief. Greater resources and more robust Medicare data need to be provided to organizations developing APM proposals to help them design APMs that will qualify as Advanced APMs.

Congress intended that providers of all types of care should have available to them two separate options for payment updates under the Physician Fee Schedule: the MIPS program and APM pathway. It also recognized that APM availability outside of ACOs was limited at the time the law was drafted. Further, Congress intended that the system of updates created under MACRA be a Part B physician payment system, and the drafters took great pains to ensure it. While ACOs provide options for specialties with hospital intensive services to qualify under the APM pathway, **we are concerned that adequate consideration was not given to ambulatory specialists like ophthalmology seeking to adopt or practice in a model of care without the need for hospital participation.**

Congress and professional organizations such as the Academy conditioned their support on MACRA based on the availability of options for specialist's interested in adopting an APM. Specialty focused payment models and medical homes were seen as one solution to this problem. Medical specialty homes are certified by accrediting bodies in much the same ways as primary care medical homes. Congress intended that specialty medical homes should be given the same consideration as primary care medical homes under both the MIPS program and APM pathway. However, while the proposed rule does provide for both primary care and medical specialty home consideration under MIPS, such allowances were not extended to models made available under the APM pathway.

**One solution to this problem is found in the steps CMS has taken to support primary care medical homes through its support of the CPC+ program.**

- **CPC+ as a Path to Specialty APMs**

CMS utilized its regulatory authority as established under the ACA and previous legislation to create the CPC+ program as a means of facilitating primary care practices. The Comprehensive Primary Care Plus (CPC+) program, built from the original CPC program, allows for alternative payments under the Medicare program in return for performance on five key areas: access and continuity, care management, comprehensiveness and coordination, patient and caregiver engagement, and planned care and population health. Such actions are in keeping with the intent of Congress and serve as an example of the level of secretarial authority granted under federal statute to promote APM adoption.

Unfortunately, the proposed rule's list of available APMs for use under the APM pathway is tailored exclusively for primary care success despite congressional intent and offers few if any options for many specialties. The actions of the Secretary in establishing the CPC+ program offers

opportunities for CMS to address this disparity in the final rule with expansion.

We encourage CMS to use the regulatory flexibility evidenced by the creation of the CPC+ program to promote specialty APM availability by including a CPC+ program for specialists under the list of available APMs. In establishing such an option, care should be given to identify those areas of care applicable to various specialists and episodes of care relevant to their practice. In addition, CMS should create rules that allow for broad adoption among various medical and surgical specialties. In order to involve stakeholders, comments on the requirements of such a program from the various specialties should be sought.

Further, CMS should engage the PTAC in recommending a set of requirements. Whether executed in a form similar to the CPC+ type program or through its coding authority similar to the establishment of the chronic care management code under the program, CMS engagement in this area can make real strides toward increasing specialty confidence in the establishment of the law by CMS.

**Finally, CMS should support specialty model adoption through the testing and adoption of a wider array of demonstrations and physician-focused payment models.** Programs such as the Oncology Care Model (OCM) are a good start, but there should be many others. As the lone APM available to specialty practitioners, much more work is needed if CMS is to support the type of broad APM development and availability Congress intended under the APM pathway. When monitoring and reviewing the performance of the OCM, CMS should work with stakeholders to identify components of the OCM that might serve as the foundation of additional model development for other chronic conditions. Those findings could then be utilized by the various medical specialties and experts in the creation of APM adoption.

### **Advanced APM Criteria**

MACRA requires Advanced APMs to meet three criteria: require participants to use certified EHR technology; provide payment for covered professional services based on quality measures comparable to those in MIPS; and require APM entities bear risk for monetary loss more than a nominal amount or be a Medical Home Model. In the proposed rule, CMS outlines its proposals for APMs to meet these criteria.

- **Use of Certified EHR Technology**

CMS proposes that 50 percent of eligible clinicians participating in an Advanced APM entity must use 2015 edition CEHRT in order to meet the first criterion. **The Academy has concerns with the proposed requirement for APM entities to use 2014 Edition CEHRT. The vast majority of providers currently use 2014 Edition CEHRT, and the**

**Academy understands that most EHR vendors are not prepared to transition to the 2015 Edition on January 1, 2017. We believe this requirement may result in an even fewer number of APM entities that qualify as Advanced**

APMs simply because the technology is not yet available. Therefore, we recommend that CMS permit eligible clinicians participating in Advanced APM Entities to utilize 2014 Edition CEHRT in 2017 and not require the use of 2015 Edition CEHRT until such technology is broadly available.

- **Payment based on Quality Measures**

**The Academy supports the flexibility proposed by CMS on what is required of Advanced APMs in order to meet this criterion. APMs should not be required to have the same reporting requirements as is required under the quality reporting category for MIPS, as each APM is designed differently and may be developed with a specific specialty or condition in mind. However, we are concerned that the proposal that payments under an APM need to explicitly vary based on quality measures in order to meet the requirements of MACRA may limit the number of APMs that can qualify as an Advanced APM. The Academy encourages CMS to broaden the proposal of how payments can be based on quality measures to allow more APMs to qualify as Advanced APMs under MACRA, including some existing models developed by the Center for Medicare & Medicaid Innovation (CMMI).**

- **Risk for Monetary Loss More than a Nominal Amount**

The third criterion that an APM must meet to be an Advanced APM is that it must either be a Medical Home Model, or bear financial risk for monetary loss in excess of a nominal amount. The Academy believes that CMS' proposed definition for nominal risk is complex and confusing. The complexity of the definition will make it difficult for eligible clinicians contemplating participation in an Advanced APM to make informed decisions. The Academy encourages CMS to simplify its definition for nominal risk so that eligible clinicians contemplating participation in Advanced APMs can understand their financial risks and if they qualify for an Advanced APM.

In addition, we are concerned that CMS' proposed definition for nominal risk may limit the number of APMs that can qualify as Advanced APMs under MACRA. The MACRA statute does not set specific risk thresholds for more than "nominal" risk. CMS proposes to define the amount of risk required to be eligible as total risk of at least four percent of the APM spending target, marginal risk of at least 30 percent, and minimum loss rate not greater than four percent.

If CMS maintains its current approach to defining more than nominal financial risk and fails to illuminate a path to guide the development and implementation of physician-focused APMs, it will preclude many promising

APMs that are under development from qualifying under MACRA. Groups like the American College of Surgeons is leading a multispecialty effort to develop a methodology that would allow APMs to group together claims from physicians in multiple practices into a comprehensive episode of care for more than 100 procedural and condition based episodes, as well as

supporting non-patient facing episodes such as anesthesiology and pathology. Without significant changes from the APM policies proposed in

the NPRM, it will be difficult for these proposals to be implemented and for Medicare patients to benefit from these care improvements.

In addition, the Academy does not believe it is appropriate to tie nominal risk requirements to the total cost of care for patients as the proposed rule does by linking it to expenditures under the APM. The four percent of total expenditures standard outlined in the proposed rule could total to a significant portion of physician practice's revenue. Total APM expenditures include costs beyond physicians' control. Physicians will be much more willing to take accountability for costs that they can affect through their own performance, such as the costs of preventable complications, than they are to take on risk for the total cost of care for a large patient population.

"More than nominal financial risk" should be defined in a way that allows the APM entity and its participating physicians to take accountability for the services they can truly influence instead of requiring physicians to take responsibility for total Medicare spending on every health problem and service their patients get. We encourage CMS to define "more than nominal risk" at a small percent of a practice's revenue, not APM expenditures. Or if it isn't feasible to tie it to participating practices, **CMS should phase-in the threshold at a lower rate and utilize a lower stop loss percentage initially. Twenty percent is still a significant amount but one that could be tolerable at the onset.** If the risk is unbearable, no entity will be willing to become an Advanced APM. If CMS maintains its proposed definition for more than nominal financial risk, promising APMs currently under development will be precluded from qualifying as Advanced APMs and any future innovation will be stymied.

### 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. The Academy supports CMS' proposal to publish the names of all eligible clinicians that are assigned to an Advanced APM. This would help prevent the issues that occurred with many of our members who learned after the fact that they were considered as participating in an APM.

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

**The Academy reiterates 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.**

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We appreciate the opportunity to comment on the CMS proposed rule regarding the Alternative Payment Model (APM) Incentive Program under the Quality Payment Program. If you have questions or need any additional information, please contact Ms. Cherie McNett, Health Policy Director at [cmcnett@aaodc.org](mailto: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,

A handwritten signature in black ink, appearing to read "Michael X. Repka". The signature is fluid and cursive, with a long horizontal stroke at the end.

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