

**Comments on the CMS Proposed Rule
Implementing the *Medicare Access and CHIP Reauthorization Act (MACRA)*
June 20, 2016
Executive Summary**

The AAFP played a central role in the development and enactment of MACRA (Public Law 114-10) and we believe this law, at its core, is designed to strengthen primary care and make primary care a strong foundation for payment and delivery reform for physician services under Medicare. As such, the importance of successful implementation for members practicing in communities across the country cannot be understated.

We also believe that MACRA, as designed by Congress, was intended to simplify the Medicare payment, quality improvement, and performance measurement programs. In the simplest terms, the law requires physicians participating in the Medicare program to implement and use an electronic health record, report quality measures on the care they provide, participate in review of their overall resource use, and engage in performance improvement activities. The law also created a glide path to move our nation's delivery and payment models away from the legacy fee-for-service system towards alternative payment models that align payment to quality and outcomes.

We applaud CMS for identifying and adhering to the fundamental provisions of the law. In general, CMS accurately identified the key elements of the law, which were to create a streamlined quality and performance program inside the fee-for-service system and create opportunities for physicians to participate in alternative payment models. We also believe that CMS has made some effort to simplify the program and to eliminate the pass/fail evaluation processes although, again, we think much work remains. The following are key areas in which we agree with the agency's proposals:

1. Quality Measurement – we believe that the regulation has simplified the quality reporting process for physicians. CMS's recommendation that physicians report on six measures is a dramatic improvement over current law. We strongly support the efforts to create a process whereby new measures can be developed, tested, and implemented.
2. Quality Reporting Opportunities – we appreciate that CMS has taken steps to ensure that physicians have a variety of options available to submit quality data to CMS. We believe the menu of options CMS presented in the regulation affords most family physicians a reasonable opportunity to engage with CMS on quality reporting activities.
3. Comprehensive Primary Care Plus Program – we strongly support the CPC+ program and we thank CMS for recognizing this primary care delivery and payment model as an advanced alternative payment model.
4. Patient Centered Medical Home – we are pleased that CMS has recognized the important role played by primary care physicians in our health care delivery system. We also appreciate that CMS included and promoted the medical home in the proposed rule.

5. Solo and Small Group Practice – we applaud CMS’s efforts to reduce the burdens placed on solo and small practices. Greater than 50 percent of our members practice in a setting with 5 or fewer physicians. These practices face enormous challenges with respect to quality reporting and health information technology and we appreciate efforts made to lessen the administrative burden placed on these practices.
6. Physician-Focused Payment Model Technical Advisory Committee – the AAFP believes the PTAC will play a vital role in the development of physician-focused delivery and payment models (PFPM) and we encourage CMS to engage and closely consider the recommendations to ensure there are more primary care Advanced APMs available in the future. We encourage CMS to evaluate models being used in other health care programs, especially in Medicare Advantage, for recognition as Advanced APMs.

While our support for MACRA remains strong, we must state that **we see a strong and definite need and opportunity for CMS to step back and reconsider the approach to this proposed rule which we view as overly complex and burdensome to our members and indeed for all physicians. Given the significant complexity of the rule, we strongly encourage CMS to issue an interim final rule with comment period rather than to issue a final rule.** The AAFP believes that our collaborative engagement with CMS has been productive and that providing a second comment period would allow us to further refine the policies to better capture those ideas and concepts that will lead to a successful program. We recognize that extending the regulatory process prolongs both the work of CMS staff and prevents full-scale implementation, but we feel an additional comment period, on balance, would be justified by the long-term success of the program.

In our response to the proposed regulation, we outline a series of recommendations by which CMS can better align the regulation with the goals and intent of the legislation. The implementation of MACRA will impact our health care system for years to come and it must be done thoughtfully, carefully, and as simply as possible – and this proposed rule at present falls short of these goals. The AAFP and our members stand ready to assist CMS in ensuring that the MACRA regulations achieve the goals established by the law and advance high quality and efficient health care for Medicare beneficiaries. We offer the following key recommendations:

Performance Period

The AAFP has been engaged in aggressive member education and practice transformation programs since the passage of MACRA in 2015. Despite these efforts, we remain concerned that a January 1 start date does not provide adequate time for education and practice adjustments that will be required to ensure the successful implementation of the quality payment programs in a majority of family physician practices. Assuming CMS issues the final rule for MACRA implementation on or around October 1, 2016, our members will need more than three months to develop a quality plan, ensure EHR functionality, identify and select relevant clinical practice improvement activities, and make necessary changes to reporting mechanisms. Physicians will need to align their Medicare activities with similar activities in Medicare Advantage, Medicaid, and the commercial insurance markets.

The period between data reporting and payment is too great. MACRA called for CMS to “make efforts” to ensure that the performance and payment periods be as close together as possible. We believe that the traditional two-year period between data submission and payment that is included in the proposed regulation neither meets Congressional intent nor achieves the goals established by the legislation. As the program matures, the sophistication of physician practices will demand more timely data reporting, so we would encourage CMS to establish a more reasonable timeframe from the beginning.

For these reasons, the AAFP urgently and strongly recommends that the initial performance period should start no sooner than July 1, 2017. While we prefer that the performance period start in 2018, we recognize that this time frame creates program administration challenges that may be insurmountable for CMS. However, based on information provided by CMS, we believe that the establishment of the payment period on July 1 allows time for the AAFP to engage in member education and allows CMS to meet its program administration requirements and the requirements of the law.

Quality measures

All measures used in MIPS and APMs must be clinically relevant, harmonized and aligned among all public and private payers, and minimally burdensome to report. The AAFP recommends that CMS use the core measure sets developed by the multi-stakeholder Core Quality Measures Collaborative to ensure alignment, harmonization, and the avoidance of competing quality measures among payers.

The AAFP believes that the reporting burden under MIPS should be equivalent for all participating physicians and that all physicians participating in the MIPS program should be required to meet the same program expectations as other MIPS participants and report on six measures. If six measures are not available in the sub-specialty list, the MIPS-eligible clinicians need to report at the higher specialty level. If six measures are still not available that are specialty specific, these MIPS-eligible clinicians should choose measures from the list of cross-cutting measures until they reach a total of six measures. If CMS requires a lower number of quality measures for a particular specialty group in MIPS, then the minimal number should be lowered for all physician specialties. We believe that parity in reporting across all physician groups is critically important.

Advancing Care Information (ACI)

The AAFP believes the current proposal for ACI has missed the mark in a major way and urges immediate reconsideration. Although we believe ACI improves on the requirements of the MU program, the burden of compliance still outweighs the benefit that patients will experience. Due to current law, we understand that CMS cannot completely abandon health IT utilization measures, yet we do believe that CMS can significantly improve and reduce administrative complexity and burden while complying with current law. The AAFP recommends a new construct for the ACI component of MIPS.

Solo and Small Group Practices – Virtual Groups

The MIPS pathway, which aims to create a quality or value-based payment model inside the traditional fee-for-service payment structure, is likely the pathway by which most physicians will be paid in the near term. Given the construct of the MIPS performance categories and the manner in which the composite score will be calculated as articulated in the MACRA Quality Payment Program's proposed rule issued by CMS, it is highly probable that physicians practicing alone or in small groups will be at a significant disadvantage under the MIPS program. CMS's own actuaries noted this in their evaluation of the proposed rule – projecting that 87 percent of solo practitioners and nearly 70 percent of those in practices of 2-9 physicians will receive a negative adjustment in 2019.

MACRA recognized that a majority of physicians practice in a clinical setting that includes five or fewer physicians. In fact, greater than 50 percent of family physicians currently practice in such a setting. In an effort to ensure that physicians practicing in such clinical settings were not negatively impacted by the provisions of the law, but in fact have an opportunity to build the capabilities to evolve and succeed under value-based and alternative payment models, Congress included several provisions aimed at providing these physicians and their practices "equal standing" with larger or more integrated groups who may be included in the MIPS cohort.

With respect to the MIPS pathway, Congress expressly established the ability of solo and small groups to aggregate their data – in an effort to remove any methodology biases due to their potential small

number of Medicare beneficiaries – through the deliberate inclusion of “Virtual Groups.” Language establishing this option was included to provide a plausible mechanism for solo and small group practices to participate and compete in the MIPS pathway against larger groups that would inherently benefit from larger numbers of beneficiaries upon which their evaluation would be conducted.

CMS, in the proposed rule, states that the agency is unable to establish or implement the virtual group option as mandated by MACRA. This is most unfortunate because not only did the law mandate that these groups be established and made available to solo and small group physicians, but it also eliminates an opportunity for these physicians to participate in an equitable manner in the MIPS program. We know that CMS has experience with the creation of new delivery models, i.e. accountable care organizations (ACOs), so we do not understand why this model has been determined complex and worthy of omission from the regulation. Virtual groups should be designed to incorporate physicians from a single or similar discipline. The geographic factor in our mind is not necessary and should be left to the physicians to determine.

The lack of virtual groups will result in a “methodology bias” between solo and small practices and larger practices, yet they all will compete against each other in the MIPS program. The result for those practices with the most limited financial reserves could be to widen the gap between them and larger practices or those affiliated with health systems. These disparities among practices based on size and location could also introduce – or exacerbate – disparities in outcomes for beneficiaries.

The virtual group policy established a reasonable approach for solo and small group physicians to begin building networks that would encourage them to progress towards more sophisticated delivery models such as medical homes and ACOs. Again, we are shocked and disappointed that this option will not be available.

Given the fact that a provision, mandated by law, to ensure the viability of solo and small physician practices in the MIPS program will not be available for such physicians and their practices in the initial performance period, we are strongly urging CMS to include an interim pathway to virtual groups, as outlined below, in the final regulation.

Physician practices with 5 or fewer physicians, billing under a single TIN, who participate in the MIPS program through the submission of quality data, use of a CEHRT electronic medical record, and participation in clinical practice improvement activities should be exempt from any negative payment updates resulting from the MIPS program until such time that virtual groups – as outlined and mandated by MACRA – are readily available. These physician practices are, however, eligible for any positive payment updates that they may warrant based upon their performance in any given performance period.

In short, any physician in a solo practice or small group that participates in the MIPS program should be eligible for positive payment updates if his or her performance yields such payments, but would be exempt from any negative payment update until a virtual group option is available. To ensure that Medicare participating physicians continue to pursue quality and performance improvement, any physician or small group that fails to participate in the MIPS required activities would be subjected to the full negative update.

We recommend that the final regulation redirect such funds necessary from the \$500 million set-aside for bonus payments to the top performers towards financing this proposed safe harbor for solo and small practices. We find it difficult to comprehend why CMS would reward an extremely small subset of Medicare participating physicians, while knowingly placing smaller practices at a distinct disadvantage.

Medical Home

MACRA, as approved by Congress, emphasized the role of advanced primary care practices. This emphasis is apparent through the inclusion of the medical home as a preferred delivery model under both the MIPS and APM pathway. It is further emphasized through legislative language that exempts medical home practices from any risk under APMs and the guarantee of maximum scoring under MIPS. It is clear to the AAFP that Congress fully supported the medical home and intended for the medical home to be a model recognized as an Advanced APM, and for good reason. The delivery of high-performing team-based patient-centered primary care is at the heart of the medical home. A significant body of evidence points to the clear trend showing that the medical home drives reductions in health care costs or unnecessary utilization, such as emergency department (ED) visits, inpatient hospitalizations and hospital readmissions. Those with the most impressive cost and utilization outcomes are generally those who participate in multi-payer programs with specific incentives or performance measures linked to quality, utilization, patient engagement or cost savings, such as the CPC initiative.

Today, nearly 50 percent of family physicians practice in a medical home. CMS's failure to make a medical home model available as an Advanced APM would not only violate Congressional intent, but would undercut more than a decade of progressive transformation in primary care practices – not to mention demoralize tens of thousands of primary care physicians. We urge CMS to identify a medical home model that can be included as an Advanced APM.

- **Recognition of Medical Homes** – While the AAFP can support the inclusion of the four nationally recognized medical home programs outlined in the regulation, we strongly recommend expansion beyond these four organizations. The AAFP believes that a physician should not be required to pay a third-party accrediting body to receive recognition as an advanced primary care practice, such as a Patient-Centered Medical Home (PCMH). The PCMH recognition or certification of a practice by an accrediting body may not accurately capture actual advanced primary care functionality. The AAFP recommends that CMS broaden the definition of PCMH specifically to include programs that have a demonstrated track record of support by non-Medicare payers, state Medicaid programs, employers, or others in a region or state. The programs to be included should be clearly articulated by CMS in advance, along with transparent criteria and methodology for the addition of new PCMH programs.

The AAFP strongly urges CMS to consider the inclusion of PCMH recognition programs that accredit based on the advanced primary care functions reflected in the Joint Principles of the PCMH and the five key functions of the CPC Initiative.

The AAFP recommends that CMS establish a process to review and grant medical home recognition authority to any entity that meets the necessary criteria as a PCMH accreditor. This would be similar to processes currently used for hospital and laboratory accreditation. The AAFP, the American Academy of Pediatrics, the American College of Physicians, and the American Osteopathic Association have joint Guidelines for Patient-Centered Medical Home Recognition and Accreditation Programs that build on the Joint Principles of the Patient-Centered Medical Home, which the four groups adopted in February 2007. CMS could use these guidelines in exercising such a deeming authority. The AAFP encourages the inclusion of state-based, payer sponsored, or regional PCMH recognition programs.

- **Financial Risk for Advanced APM Medical Homes** – The AAFP strongly recommends that CMS remove the Medical Home Model financial standard in its entirety from the proposed rule and reiterates our strong belief that medical homes should not be subject to any financial risk. The AAFP views this as a significant misinterpretation of the law which was designed to protect and foster medical homes.

The financial standard for the Medical Home Model is an arbitrary imposition of financial risk placed upon clinicians in these models and violates the intent of the law. We call on CMS to eliminate the 50-practice limitation placed on the medical home exemption as nothing in MACRA suggests that the medical home exemption from risk should be subjected to any limiting factor.

The medical home is the crux of a value-based health care system. In its most recent Annual Review of Evidence of the PCMH's impact on cost and quality, the Patient-Centered Primary Care Collaborative identifies several PCMH programs that have reduced costs and improved quality. From these findings, 21 of 23 programs reporting on cost measures found reductions in one or more measures, and 23 of 25 reporting on utilization measures found reductions in one or more measures.

Because the PCMH reduces spending and utilization, imposing risk sharing on the Medical Home Model may be counterproductive and have a dampening effect on adoption of the model. Indeed, it is because of the medical home's importance to the success of the value-based payment model that they were provided protection under the law.

- **Limited Advanced APMs for Family Physicians** – The AAFP is concerned that CMS did not meet Congressional intent with respect to ensuring a medical home option be made available as an Advanced APM. As previously stated, we believe that Congress intended and, through the risk exemption, demonstrated a commitment to the inclusion of a medical home opportunity in the Advanced APM pathway. It is clear to us that the intent of the law was to incentivize medical home expansion by stating that “Medical Homes that meet criteria comparable to medical homes expanded under section 1115A(c) should qualify as an [advanced] APMs.” We would note that the legislative text states “comparable to” not “an expansion of” programs under 1115A(c).

The AAFP recommends two immediate actions on the part of CMS to ensure that a medical home opportunity exists under the Advanced APM pathway:

CMS should initiate an expedited analysis of the results of the CPC initiative to determine whether the statutory requirements for expansion by the Secretary are met. This analysis should be completed no later than January 1, 2018 to allow for a determination to expand CPC in time for medical home practices to qualify as Advanced APMs in 2019.

CMS should establish and implement a deeming program that enables practices enrolled in medical home programs run by states (including state Medicaid programs), Medicare Advantage, other non-Medicare payers, and employers as being deemed to have met criteria “comparable to medical homes expanded under section 1115A (c).” This deeming process should be defined and implemented prior to January 1, 2018.

Total Cost of Care and MSPB Measures

The AAFP strongly opposes application of the total per-capita cost of care and Medicare Spending per Beneficiary (MSPB) measures to primary care physicians that are not part of an advanced APM. Both total cost of care and MSPB were developed to measure hospital performance, and these measures inappropriately attribute costs of patient care that are unrelated to physician practice and particularly, unrelated to primary care practice.

The AAFP urges CMS to withdraw these measures and instead use care episode-based groups as the sole method of measuring Resource Use to emphasize high volume and high cost conditions and

procedures. The AAFP insists that attribution for patients within care episode groups should be to the physician with the highest Part B allowable charges, defined within the proposed rule as a plurality of claims, rather than the methodology suggested in this proposed rule.

Physicians that are part of an Advanced APM have agreed to be responsible for total costs and have incentives and mechanisms available to review, manage and reduce total costs. However, physicians outside such arrangements have limited control over the actions and costs of specialists, are offered no incentives for reducing total costs, and have no agreed-upon goals or mechanisms in place to review, manage and reduce total costs. Primary care physicians outside advanced APM arrangements cannot anticipate that multiple specialties will work together toward total cost of care reduction and should not be held accountable for these costs, many of which will be generated by specialists. Rather, the physicians who generated the costs should be held responsible for such costs.

MIPS APM category

The AAFP objects to the implementation of the entire section of this proposed rule related to “MIPS APMs.” This section of the proposed regulation is incredibly confusing and we have concerns that, as written, CMS is incentivizing physicians to remain in the fee-for-service program rather than to continue their progress towards APMs. In concept, we believe physicians and practices should proceed towards Advanced APMs versus slipping back into the fee-for-service program. CMS and CMMI have implemented policies in the MSSP program that allow ACO's to maintain a neutral financial position for a defined period of time. We believe that this approach may be appropriate in this regulation – allow APMs to sit between the two programs, not eligible for the 5 percent Advanced APM bonus, but not subject to the MIPS methodology either for a period of time such as two years. At the completion of this time period, the APM would either have to move into the full Advanced APM program or be subjected to the MIPS criteria as applicable with no special consideration under any of the four categories.