June 24, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–5517–P
P.O. Box 8013
Baltimore, MD 21244–8013

Dear Acting Administrator Slavitt:

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,900 family physicians and medical students across the country, I write in response to the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models proposed rule as published by HHS in the May 9, 2016 *Federal Register*. This proposed rule describes how CMS intends to implement key portions of the bipartisan *Medicare Access and CHIP Reauthorization Act* (MACRA), which repealed the Medicare sustainable growth rate methodology in favor of a new approach to paying physicians and others for the value and quality of care they provide.

The AAFP played a central role in the development and Congressional passage of MACRA and we continue to support the core reforms set forth in MACRA. 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 glidepath 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 support numerous provisions included in the regulation. Overall, we applaud CMS for identifying and adhering to the fundamental provisions of the law. In general, CMS accurately

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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. Your recommendation that requires physicians to report on 6 measures is a dramatic improvement over current law. Furthermore, we strongly support your efforts to create a process whereby new measures and groups of 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 you have 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 you have included and promoted the medical home in the proposed rule.

5. Solo and Small Group Practice – we applaud your efforts to reduce the burdens placed on solo and small practices. Greater than 50% 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. Furthermore, 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.

Furthermore, in our response to the proposed regulation, we outline a series of recommendations by which CMS can make significant improvements to the regulation to 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 for your consideration:

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. Furthermore, physicians will need to align their Medicare activities with similar activities in Medicare Advantage, Medicaid, and the commercial insurance markets.

Additionally, we are deeply concerned that 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 you 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. To accomplish this, 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.

Additionally, the AAFP believes that the reporting burden under MIPS should be equivalent for all participating physicians. To accomplish equivalency in the reporting burden, we believe 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.

Public Law 114-10 recognized that a majority of physicians practice in a clinical setting that includes 5 or fewer physicians. In fact, greater than 50% 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 "Virtual Groups." The inclusion of virtual groups was quite deliberate. 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 Public Law 114-10. 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. ACOs, so we do not understand why this model has been determined

complex and worthy of omission from the regulation. As we noted in our RFI response, 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.

Furthermore, 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 accountable care organizations. 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 Public Law 114-10 – 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, physicians 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 such time that the 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.

Furthermore, 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 Comprehensive Primary Care 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). In addition, 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 patient-centered medical home 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 Patient-Centered Medical Home (PCMH) and the five key functions of the Comprehensive Primary Care (CPC) Initiative.

The AAFP recommend 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 developed and adopted in February 2007. CMS could use these guidelines in exercising such a deeming authority. In addition, 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. Furthermore, we call on CMS to eliminate the 50-practice limitation placed on the medical home exemption. Again, nothing in the law 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:

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

Thank you for the opportunity to work with you to stand up a program that meets the needs of Medicare beneficiaries, their physicians, and the Medicare program. We remain steadfast in our desire to see this law succeed. To improve the final rule, we offer the following summary and detailed comments.

E. MIPS Program Details

1. MIPS-Eligible Clinicians

a. Definition of a MIPS-Eligible Clinician

CMS proposes to define a MIPS-eligible clinician (at §414.1305) as a physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), and a group that includes such professionals. CMS intends to consider using its authority under section 1848(q)(1)(C)(i)(II) of the Act to expand the definition of MIPS-eligible clinician to include additional clinicians (as defined in section 1848(k)(3)(B) of the Act) made eligible through rulemaking in future years. Additionally, CMS proposes (as defined at proposed §414.1305) to allow those not yet subject to MIPS adjustments the option to report voluntarily measures and activities for MIPS. Those who choose to voluntarily report on applicable measures and activities specified under MIPS, would not receive a MIPS payment adjustment but would use this opportunity to learn the

program. CMS is particularly interested in public comment regarding the feasibility and advisability of voluntary reporting in the MIPS program for entities such as Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), including comments regarding the specific technical issues associated with reporting that are unique to these health care providers.

AAFP Response
The agency's proposal is entirely consistent with the statute as amended by MACRA. The statute did not provide CMS much, if any, latitude in this regard. We appreciate that CMS is allowing eligible clinicians who are not MIPS-eligible clinicians the option to voluntarily report measures and activities for MIPS without applying an adjustment under MIPS to them. We do not expect many eligible clinicians will take advantage of this opportunity but in general, we are supportive of the agency's proposal.

b. Non-Patient-Facing MIPS-Eligible Clinicians
CMS proposes (at §414.1305) to define a non-patient-facing MIPS-eligible clinician as an individual MIPS-eligible clinician or group that bills 25 or fewer patient-facing encounters during a performance period. CMS considers a patient-facing encounter as an instance in which the MIPS-eligible clinician or group billed for services such as general office visits, outpatient visits, and surgical procedure codes under the PFS. CMS intends to publish the proposed list of patient-facing encounter codes on a CMS website similar to the way it currently publishes the list of face-to-face encounter codes for the Physician Quality Reporting System (PQRS). This proposal includes telehealth services in the definition of patient-facing encounters. CMS considered other options, such as a set percentage of patient-facing encounters or physician specialty. CMS seeks comments on these alternative approaches, too. As described elsewhere in the proposed rule, CMS proposes to apply the Secretary's authority under section 1848(q)(5)(F) of the Act to reweight the score for certain performance categories to zero if there is no performance category score for non-patient-facing MIPS-eligible clinicians or to lower the weight of the score for the quality performance category if there are not at least three scored measures.

AAFP Response
The AAFP concurs with the patient-facing threshold of 25 encounters.

d. MIPS-Eligible Clinicians Who Practice in RHCs and FQHCs
CMS proposes that services rendered by an eligible clinician that are payable under the RHC or FQHC methodology would not be subject to the MIPS payments adjustments. However, such an eligible clinician would have the option to voluntarily report on applicable measures and activities for MIPS and the data received would not be used to assess performance for the purpose of the MIPS adjustment.

AAFP Response
This proposal seems reasonable to the AAFP.

e. Group Practice (group)
As discussed in section II.E.2.b of this proposed rule, CMS proposes to define a group at §414.1305 as a single Taxpayer Identification Number (TIN) with two or more MIPS-eligible clinicians, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN. Also, as outlined in section II.E.2.c. of this

proposed rule, CMS proposes (at §414.1305) to define an APM entity group as one identified by a unique APM participant identifier.

AAFP Response
We support this proposal. As noted, it is consistent with the approach that CMS currently uses under PQRS and the Value Modifier (VM), so physicians are already familiar with the concept. Further, if individual MIPS-eligible clinicians are to be identified by a combination of TIN and NPI, it makes sense that groups would be identified solely by a TIN. Finally, as noted, this is preferable to creating a new MIPS-specific identifier for groups.

We are unclear on CMS's proposal (at §414.1305) to define an APM entity group by a unique APM participant identifier. The proposed identifier for individual APM participants appears to be an alpha/numeric identifier of up to 35 characters, which is almost twice as long as the TIN/NPI combination we recommend for MIPS-eligible clinicians. We are unclear why an eligible clinician who is a participant of an APM could not simply be identified by a combination of TIN, EP NPI, and a single character prefix or suffix to denote the eligible clinician is part of an APM entity. We do not understand why the individual clinician would have to use such a long and cumbersome identifier.

It makes sense that APM entities would be identified by a combination of APM identifier and APM entity identifier (similar to the TIN/NPI combination for individual eligible clinicians). We also think it makes sense for CMS to be able to link individual eligible clinicians with APM entities, but it seems a stretch to go from there to what CMS proposes in this regard.

2. MIPS-Eligible Clinician Identifier
CMS is not proposing to create a new identifier for the MIPS-eligible clinician. Instead, CMS is proposing to use multiple identifiers that allow an MIPS-eligible clinician to be measured as an individual or collectively through a group's performance. CMS also proposes that the same identifier be used for all four performance categories: Quality, Resource Use, Clinical Practice Improvement Activity (CPIA), and Advancing Care Information (ACI). As discussed in section II.E.6 of the proposed rule, the Composite Performance Score (CPS) methodology section, while CMS will have multiple identifiers for participation and performance, it proposes to use a single identifier—TIN/NPI—for applying the payment adjustment, regardless of how the MIPS-eligible clinician is assessed.

AAFP Response
We appreciate that CMS proposes not to establish a new identifier for the MIPS-eligible clinician. In our response to the MACRA request for information (RFI), we stated that the AAFP opposes the establishment of a new identifier, because it is not needed and would only add to the daily administrative complexity physicians face. Another disadvantage of creating a new distinct MIPS identifier would be the requirement to use a crosswalk to link MIPS data to other data sets.

We also appreciate the proposal that the same identifier be used for all four performance categories. This proposal is preferable, from the perspective of administrative simplicity, to varying the identifier from one category to the next, which is effectively the case under the current programs [i.e., PQRS, VM, and Electronic Health Record (EHR)- Incentive Program/Meaningful Use (MU)].

a. Individual Identifiers

CMS proposes to use a combination of billing TIN/NPI as the identifier to assess performance of an individual MIPS-eligible clinician.

AAFP Response
We support this proposal. In our response to the MACRA RFI, the AAFP recommended that CMS use a combination of the MIPS-eligible clinician's TIN and NPI, as the agency does in the PQRS. A combination of these existing identifiers will enable easier identification of MIPS-eligible clinicians for research purposes, as well as easier linkage of the MIPS program data to other data sets for research purposes. Additionally, most physician practices are accustomed to using the existing NPI and TIN identifier system. The TIN and NPI combination also allows for the identification of group practices.

b. Group Identifiers for Performance
CMS proposes to use a group's billing TIN to identify a group, which is the approach that has been used as a group identifier for both PQRS and VM. CMS further proposes (at §414.1305) to codify the definition of a group as a group that would consist of a single TIN with two or more MIPS-eligible clinicians (as identified by their individual NPI) who have reassigned their billing rights to the TIN.

AAFP Response
We support this proposal. It is consistent with the current CMS approach under PQRS and the VM, so physicians are already familiar with the concept. Further, if individual MIPS-eligible clinicians are to be identified by a combination of TIN and NPI, it makes sense that groups would be identified solely by the TIN. Finally, as noted, this is preferable to creating a new MIPS-specific identifier for groups.

c. APM Entity Group Identifier for Performance
CMS proposes that each eligible clinician who is a participant of an APM entity would be identified by a unique APM participant identifier, which would be a combination of four identifiers:

(1) APM identifier (comprised of 6 alpha characters established by CMS; e.g., XXXXXX);
(2) APM entity identifier (10 alphanumeric characters established under the APM by CMS; e.g., XX00001111);
(3) TIN(s) (9 numeric characters; e.g., 000001111);
(4) EP NPI (10 numeric characters; e.g., 0000011111).

CMS also proposes (at §414.1305) to codify the definition of an APM entity group as "the group of eligible clinicians participating in an APM entity, as identified by a combination of the APM identifier, APM entity identifier, Taxpayer Identification Number (TIN), and National Provider Identifier (NPI) for each participating eligible clinician."

AAFP Response
As noted above, we are unclear on CMS's proposal in this regard. The proposed identifier for individual APM participants appears to be an alphanumeric identifier of 35 characters, which is almost twice as long as the TIN/NPI combination we would recommend for MIPS-eligible clinicians. We are unclear why an eligible clinician participating of an APM entity could not simply be identified by a combination of TIN, EP NPI, and possibly a single character prefix or suffix to denote the eligible clinician is part of an APM entity. We do not understand why the individual clinician would have to use such a long and cumbersome identifier.

It makes sense that APM entities would be identified by a combination of APM identifier and APM entity identifier (similar to the TIN/NPI combination for individual eligible clinicians). We also think it makes sense for CMS to be able to link individual eligible clinicians with APM entities, but it is a significant administrative burden to go from there to what CMS proposes in this regard.

3. Exclusions

a. New Medicare-Enrolled Eligible Clinician

Consistent with sections 1848(q)(1)(C)(v) and (vi) of the Act, CMS proposes that a new Medicare-enrolled eligible clinician be defined as a professional who first becomes a Medicare-enrolled eligible clinician within the Provider Enrollment, Chain and Ownership System (PECOS) during a year-long performance period and who has not previously submitted claims as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier. These eligible clinicians will not be treated as a MIPS-eligible clinician until the subsequent performance period. CMS also proposes that in no case would a MIPS adjustment factor (or factors) apply to the items and services furnished by new Medicare-enrolled eligible clinicians.

AAFP Response

The agency's proposal is entirely consistent with the statute as amended by MACRA. The statute intentionally did not provide CMS latitude in this regard.

b. Qualifying APM Participants (QP) and Partial Qualifying APM Participant (Partial QP)

CMS proposes (at §414.1310) that the definition of a MIPS-eligible clinician does not include qualifying APM participants (defined at §414.1305 and Partial QPs defined at §414.1305) who do not report on applicable measures and activities that are required to be reported under MIPS for any given performance period.

AAFP Response

The agency's proposal is entirely consistent with the statute as amended by MACRA. The statute intentionally did not provide CMS latitude in this regard.

c. Low-Volume Threshold

CMS proposes at §414.1305 to define MIPS-eligible clinicians or groups who do not exceed the low-volume threshold as an individual MIPS-eligible clinician or group if, during the performance period, they have Medicare billing charges less than or equal to $10,000 and provide care for 100 or fewer Part B-enrolled Medicare beneficiaries (*emphasis added*). CMS believes this is a value-oriented strategy because it retains as MIPS-eligible clinicians those who are treating relatively few beneficiaries, but who engage in resource-intensive specialties, or those who are treating many beneficiaries with relatively low-priced services. By requiring the $10,000 and providing care for 100 or fewer Part B-enrolled Medicare beneficiaries criteria to be met, CMS believes it can meaningfully measure performance and drive quality improvement across the broadest range of clinician types and specialties. Conversely, it excludes MIPS-eligible clinicians who do not have a substantial quantity of interactions with Medicare beneficiaries or furnish high-cost services.

AAFP Response

We appreciate the agency's intent with its proposed definition. However, we question the proposed reliance on a combination of billing charges and the number of Part B-enrolled Medicare beneficiaries. Under MIPS, eligible clinicians will be evaluated based on Quality, Resource Use, CPIA, and ACI. The statistical reliability of the measures used in those areas depends on the number of cases in the denominator, which is almost always the number of beneficiaries rather than allowed charges. Under the agency's definition, an eligible clinician who provides $11,000 in billing charges to five Part-B enrolled Medicare beneficiaries would not be excluded based on the low-volume threshold. However, neither we nor CMS should have any confidence in the measures of Quality and Resource Use from a sample of five beneficiaries. Accordingly, we strongly recommend that CMS define MIPS-eligible clinicians or groups who do not exceed the low-volume threshold as an individual MIPS-eligible clinician or group who, during the performance period, provides care for less than 125 Part B-enrolled Medicare beneficiaries. At the level of 125 or more Part B Medicare beneficiaries seen, we and CMS can have confidence in the measures of Quality, Resource Use, etc. without regard to the billing charges involved.

As an aside, we note that section 1848(q)(1)(C)(iv)(III) refers to the minimum amount (as determined by the Secretary) of allowed charges billed by such professional under this part for such performance period," so CMS should use the term "allowed charges" rather than "billing charges" to be consistent with the statute when discussing this provision. Further, "allowed charges" is a more commonly used and understood term and a more accurate reflection of the eligible clinician's actual volume of Medicare business, which is another reason that the proposed use of "billing charges" is problematic.

d. Group Reporting

(1) Background

CMS proposes that:

- Individual MIPS-eligible clinicians may have their performance assessed as a group if the group is a single TIN associated with two or more MIPS-eligible clinicians, as identified by a NPI, that have their Medicare billing rights reassigned to the TIN;
- To have its performance assessed as a group, a group must meet the proposed definition at all times during the performance period for the MIPS payment year;
- To have their performance assessed as a group, individual MIPS-eligible clinicians within a group must aggregate their performance data across the TIN; and
- A group that elects to have its performance assessed as a group would be assessed as a group across all four MIPS performance categories.

AAFP Response

All of the CMS proposals in this regard seem reasonable, and the AAFP supports them.

(2) Registration

CMS proposes to eliminate a registration process for groups submitting data using third-party entities (e.g., qualified clinical data registry (QCDR) or health IT vendor). Specifically, CMS proposes that a group must adhere to an election process established and required by CMS. CMS does not propose to require groups to register to have their performance assessed as a group except for groups submitting data on performance measures via participation in the CMS Web Interface or groups electing to report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey. For all other data submission methods, groups must work with appropriate third-party entities to ensure the data submitted clearly indicates that the

data represents a group submission rather than an individual submission. For groups to elect participation via the CMS Web Interface or administration of the CAHPS for MIPS survey, CMS proposes that such groups must register by June 30 of the applicable 12-month performance period (that is, June 30, 2017, for performance periods occurring in 2017).

AAFP Response
We appreciate that CMS proposes to eliminate the necessity of a registration process for groups submitting data using third-party entities and instead, allowing them to work with appropriate third-party entities to ensure the data submitted clearly indicates that the data represents a group submission rather than an individual submission. We view this as a step in the direction of administrative simplification for many physician groups.

We understand the need for groups to register to elect participation via the CMS Web Interface. In this scenario, CMS essentially functions as the third-party entity and thus, requires registration as a condition of using its reporting mechanism. Besides, we note that this reporting option is voluntary. That said, we are most uncomfortable with CMS setting the registration deadline for this option at June 30, 2017and recommend that CMS make the deadline September 30 instead. We believe September 30 provides CMS with sufficient time (i.e., 90 days) to process groups' registration via the CMS Web Interface.

We do not understand the necessity for groups to register to elect to report the CAHPS for MIPS survey or the necessity of setting a June 30 deadline for such registration. As we understand it, groups who choose this option also will use a third-party entity (i.e., a CMS-approved survey vendor), so we fail to see why such groups must be treated differently from groups who choose to use other CMS-approved third-party vendors, such as qualified registries, health IT vendors, and QCDRs. Further, we think the deadline for signing up with CAHPS survey vendors should be between the group and the vendor, not CMS. We note that, per the proposed rule, the group will need to use another submission mechanism (like qualified registries, QCDRs, EHR, etc.) to complete the quality data submission, which further suggests that these groups are no different from those whom CMS will otherwise exempt from the registration process. Absent a clear and compelling rationale for requiring CAHPS for MIPS survey users to register, we strongly recommend that CMS exempt them from the registration process like other groups using third-party entities.

e. Virtual Groups
(1) Implementation
CMS proposes that implementation of virtual groups for the calendar year 2017 performance period is infeasible "as a result of the insufficient timeframe to develop a web-based registration process." Instead, CMS proposes implementation of a web-based registration system for calendar year 2018 to provide the necessary time to establish and implement an election process and requirements applicable to virtual groups, and enable proper system development and operations. CMS intends to address all of the requirements pertaining to virtual groups in future rulemaking and requests comments on factors it should consider regarding the establishment and implementation of virtual groups.

AAFP Response
The AAFP is extremely disappointed that CMS has not proposed the rules for implementing virtual groups. However, we can understand CMS's proposal to delay implementation of virtual groups in light of the agency's workload relative to its available resources. Our members will experience similar "bandwidth" issues when it comes to implementing MACRA in their practices,

which is exactly the reason why we call for a similar delay in the proposed start of the initial performance period later in this letter.

There are at least two negative consequences to the proposed delay in implementation of virtual groups. First, a delay violates the statute. Section 1848(q)(5)(I)(ii) of the Act states:

> *The Secretary shall, in accordance with the requirements under clause (iii), establish and have in place a process to allow an individual MIPS-eligible professional or a group practice consisting of not more than 10 MIPS-eligible professionals to elect, with respect to a performance period for a year to be a virtual group under this subparagraph with at least one other such individual MIPS-eligible professional or group practice.*

In other words, the law requires CMS to have in place a virtual group election process with respect to a performance period. However, CMS is implementing a performance period, 2017, without this statutorily required process.

The other negative consequence of CMS's inaction here is that solo and small group physicians who had been counting on the virtual group option to be successful under MIPS will not have the opportunity. The AAFP is committed to the implementation and eventual success of virtual groups. Our members are inquiring about it and viewed it as an option to band together to share resources while maintaining their independence as solo physicians and small groups. The AAFP is ready to help them.

Unfortunately, the lack of a virtual group option is harmful to such practices that were otherwise ready to engage MACRA in this way, and we are concerned that they will be among those hardest hit when CMS implements MIPS in 2017. Thus, we strongly urge CMS to allow for a safe harbor that would exempt solo and small group practices (i.e., five or fewer eligible clinicians) from MIPS until the virtual group option is in place. This would allow such practices to receive a minimum 0 percent update (e.g., they could receive bonuses if they are high performers) To finance this "hold harmless" provision, CMS should use a percentage of the $500 million otherwise allocated to high performers under MIPS. Furthermore, CMS should prioritize technical assistance funding for those affected by virtual group delay.

We also note that it is consistent with the way in which CMS has implemented the VM for solo physicians and small group practices by holding them harmless from negative adjustments during the first year in which the VM applied to them.

When CMS does, in fact, get around to implementing virtual groups in future rulemaking, then we would offer the same guidance we provided the agency almost six months ago in response to its request for information on MACRA. Specifically, for virtual groups, eligibility, participation, and performance should be assessed no differently than any other groups under MIPS. The AAFP believes voluntary virtual groups should be able to collaborate as a team in order to transform health care delivery. Virtual groups can demonstrate this by signing an agreement with a payer, outlining performance expectations, as well as risk and reward parameters. The program should be balanced such that quality and cost performance are rewarded.

Virtual groups should have a unique, newly created identifier to enable effective identification of the group. If a virtual group consists of a subset of EPs for one TIN, CMS needs to be able to identify the subset that is part of the virtual group separate from the entire TIN. However, at

least in the early years of the program, for the sake of administrative simplicity, the AAFP encourages CMS not to allow TINS to split.

To encourage the creation and growth of virtual groups, the AAFP calls on CMS to allow virtual groups to consist of multiple TINs or for multiple TINs to be classified under a new TIN specific to the new virtual group. The AAFP foresees virtual groups forming in a variety of settings and circumstances, and we encourage CMS not to be overly prescriptive on the administrative structure of these groups.

If CMS allows TINs to split and individual members of a TIN have decided not to join the virtual group, they should be considered as individual EPs, unless CMS has some means to consider them collectively apart from the individuals in the TIN who joined the virtual group.

The AAFP believes CMS should not establish thresholds based on the eligible number of patient-lives attributed to the virtual group and not arbitrarily dictate and restrict the number of providers participating in a virtual group.

As virtual group programs have already been established and have demonstrated favorable quality and cost performance before the implementation of MACRA, the AAFP believes there should not be a limit on the number of virtual groups in the first year. Furthermore, the AAFP sees virtual groups as an opportunity for small group practices to be successful under MACRA. Limiting the availability of this pathway would restrict opportunities for small and independent practices.

The AAFP recommends CMS allow prospective virtual groups to demonstrate through an application process that they have reliable mechanisms in place for establishing patient attribution, as well as for reporting under MIPS throughout the performance period. These mechanisms could include the virtual group receiving patient consent prospectively in a manner similar to the requirements of the chronic care management services. Alternatively, it could include the option for virtual groups to demonstrate patient attribution through previous claims submitted by providers within the virtual group. Either method enables practices in the virtual group to prospectively know which patients are attributed to the group and how the virtual group is performing in real time, allowing—if needed—practices to modify their actions during the performance period and make improvements. We encourage CMS not to be restrictive in how virtual groups demonstrate this and instead allow flexibility for innovative proposals from virtual groups as part of the anticipated application process.

Since CMS and physician practices already offer a way for multi-specialty groups to come together through the Medicare Shared Savings Program, as well as other options for accountable care organizations, the AAFP urges CMS to limit virtual groups to practices of the same or similar specialties. We view the design of virtual groups as intending to increase the number of patients for quality evaluation, which is best done by single or similar disciplines to facilitate comparison. The AAFP believes any limitations should be based on the chosen population, its size, and location, instead of arbitrary mileage restrictions or state boundaries. Since patient populations can be widely dispersed or closely compacted depending on the geographic area, CMS should consider population density or other geographic limitation based on the location of the virtual group.

(2) Election Process
CMS proposes to establish an election process that would end on June 30 of a calendar year before the applicable performance period. During the election process, CMS proposes that individual MIPS-eligible clinicians and groups electing to be a virtual group would be required to register in order to submit reportable data. Virtual groups would be assessed across all four MIPS performance categories. CMS intends to address all elements relating to the election process in future rulemaking.

AAFP Response
CMS offers no rationale for the proposed June 30 deadline to elect to register as a virtual group. Consequently, it is not clear why groups must make that decision a full six months in advance of the performance year. We propose that CMS set the deadline at September 30 instead, which would still give the agency 90 days before the applicable performance period, assuming the performance period began on January 1.

We have no problems with the proposal that individual MIPS-eligible clinicians and groups electing to be a virtual group would be required to register in order to submit reportable data.

4. MIPS Performance Period
CMS proposes MIPS claims data used in MIPS that such claims would need to be processed no later than 90 days after the end of the applicable performance period for information to be used in calculations. If 90 days is not feasible, then CMS would use 60 days. If 90 or 60 days are not possible, then CMS would use claims that are paid within 60 days after 2017 for payment adjustment in 2019.

CMS also proposes that the performance period under MIPS would be the calendar year (Jan. 1- Dec. 31) two years prior to the payment year. If a MIPS-eligible clinician switches practices during the performance year, or does not have a full year of data, they are required to report what they do have.

Additionally CMS discusses an alternative approach for future years for assessment of individual MIPS-eligible clinicians with less than 12 months of performance data in the performance year. For example, if CMS could identify such MIPS-eligible clinicians and confirm there are data issues that lead to invalid performance calculations, then CMS could score the MIPS-eligible clinician with a CPS equal to the performance threshold, which would result in a payment adjustment of zero.

Finally CMS seeks input on how to account for MIPS-eligible clinicians that take extended leave (i.e., illness, vacation and holidays) that may affect sample size.

AAFP Response
We appreciate the need for a 90-day period for claims data run-out as opposed to the 60 days currently given in the PQRS.

The AAFP continues to be very concerned about the approach CMS has outlined in the proposed rule for the definition of the performance period, the process for providing accurate and actionable data to physicians on their performance, and CMS' approach for assuring that the payment period for physicians is based on the most up-to-date information on each physician's performance. We believe CMS has the ability and resources to take concrete steps to address these issues and assure that primary care physicians are appropriately evaluated

and compensated as they align their practices and commit resources to implement the MACRA provisions.

As AAFP requested in our letter to CMS prior to the release of the proposed rule, we urgently and strongly call on CMS to consider taking the following steps. First, CMS must use 2018 as the initial assessment period for MACRA, and under no circumstances should the initial performance period start any earlier than July 1, 2017. This important step would allow sufficient time for all physicians, in practices small and large, in urban and rural areas, to engage on the key policy elements of MACRA, and this step simultaneously would shorten the gap between the performance period and the payment period. With this step, CMS would assure that primary care physician payment is linked to the most accurate and timely data.

Assuming CMS issues the final rule for MACRA implementation on or around November 1, 2016, our members will need more than two months to select quality measures, identify relevant CPIA, and make necessary changes to reporting mechanisms, etc. This will be especially true for those members not currently engaged in PQRS and/or Meaningful Use. Perhaps 2017 could be seen and designated as a year for reporting only, in preparation for 2018 to be a year of judgement. If this is not possible, we call on CMS to use, at the very least, the second half of 2017 (July 1, 2017 – December 31, 2017) as the initial assessment period for physicians, whether they are participating via the MIPS or APM pathways. This approach would assure CMS has adequate time and resources to provide physicians with data on their performance metrics—a key facet of promoting steps for physicians to assess their own performance and make decisions about participation in MACRA.

The AAFP supports the proposed exclusion from MIPS adjustment for eligible clinicians with less than 12 months of performance data.

Regarding extended leave by MIPS-eligible clinicians, the AAFP is concerned that the use of extended leave might result in gaming by clinicians if they intentionally fall below the low-volume threshold. We would encourage CMS to watch for a pattern of gaming and, if that is the case, act accordingly.

5. MIPS Category Measures and Reporting
a. Performance Category Measures and Reporting
CMS proposes that MIPS-eligible clinicians can submit information via multiple mechanisms, but while they must use one submission mechanism per category, no submission method is required for the Resource Use category since CMS will use claims data. CMS believes it would reduce administrative burden for clinicians if they submitted CPIA, Quality, and ACI through the same mechanism. The proposed rule notes that not all third-party entities will be ready to support practices in this first year.

CMS seeks comment on the use of future rulemaking that requires health IT vendors, QCDRs, and qualified registries to have capabilities to submit all categories.

The agency seeks comments on providing bonus points in the quality scoring section for MIPS-eligible clinicians who submit quality measures through a qualified registry, QCDRs, Web interface, or certified electronic health record technology (CEHRT) submission.

AAFP Response
The AAFP agrees that both individual MIPS-eligible clinicians and groups should be able to submit quality, CPIA, and ACI data via a qualified third party (defined as a qualified registry, QCDR, or EHR submission). We agree that individual MIPS-eligible clinicians should be able to report quality data via Medicare Part B claims and report CPIA and ACI data via attestation, and agree that groups should be able to report CPIA and ACI data via attestation.

We appreciate the fact that eligible clinicians will be allowed to report performance data using different submission methods. If an eligible clinician submits data via multiple mechanisms, we agree that CMS should score all options and use the highest performance score.

However, while we appreciate the fact that ONC points out it may reduce administrative burden to report quality, CPIA and ACI performance data by using the same single third-party submission mechanism, we do not support a requirement in future years for a single submission mechanism for all three of these performance categories. Not only is it likely not possible, as ONC points out, that vendors would be able to become qualified to submit data for each of these performance categories within the first year, but it is also possible that a vendor has no desire to become qualified to submit data for all three of these performance categories. It is also possible that eligible clinicians and groups may prefer to continue to report quality, CPIA, and ACI data via separate submission mechanisms. We continue to support modular qualification of third-party intermediaries, who will become qualified for only those performance categories for which they will submit data on behalf of eligible clinicians. Likewise, we continue to support freedom of choice for eligible clinicians and groups in the submission mechanism to be used for each different performance category. We do, however, recommend that ONC disseminate clear messaging to third-party data submission intermediaries that it could behoove them to become qualified to submit data for the three performance categories of Quality, CPIA, and ACI data, as reporting these three categories via the same submission mechanism may reduce administrative burden for eligible clinicians; thus, there is a strong potential for increased market demand for third-party data submission intermediaries qualified to submit data for all three performance categories. If eligible clinicians prefer to use a single vendor for submission of all categories of data, they could then opt to select a vendor that is qualified to submit data for each performance category. However, if it makes more sense for an eligible clinician to continue to utilize vendors or third parties already in place, each qualified to report on different categories, rather than to purchase new technology or enter into new contractual relationships simply to obtain a single third-party qualified to report all categories of data, they are then able to do so. This would also limit eligible clinicians from having to pay for functionality that the vendor did not need to provide to its clients.

We agree that it makes sense for all eligible clinicians choosing to report within a group (other than a virtual group), rather than individually, that they should report using the same single submission mechanism for a given performance category. Any circumstances that would pose challenges in doing so (that would affect whether to report individually or in a group) could usually be reasonably foreseen before decision-making by the eligible clinician. However, because group practice membership has the potential to change within a reporting period (i.e., eligible clinicians may leave or join another practice), it is recommended that the final rule address terms of reporting for these scenarios, regardless of whether a third-party intermediary is used for data submission or whether the eligible clinician or group is reporting performance scores independently.

The following scenarios should be addressed:

- An eligible clinician reporting within a group leaves the group practice and begins reporting independently.
- An eligible clinician reporting within a group leaves the group practice and begins reporting within a new group.
- An eligible clinician reporting individually joins a group and wishes to begin reporting within the group.

In each of the above scenarios, eligible clinicians can face significant challenges with data accessibility and the ability to report timely due to both the technological reporting difficulties inherent with having data present in different EHR systems, as well as potentially experiencing inability, or delayed ability, to retrieve their performance data from a practice or health system that they have left. The final rule should address situations in which the eligible clinicians' experiences access barriers to their performance data held by prior practice partners or employers, and the eligible clinician should be held harmless under these circumstances.

In regard to promoting use of CEHRT and QCDR's, while CMS may be required to encourage the use of a particular data submission reporting modality, eligible clinicians should retain the choice in determining the best submission mechanism for them. Thus, any particular option provided for data submission should not be disincentivized.

Additionally, in the MIPS and APMs Request for Information, several commenters voiced concerns about the capabilities and data quality of QCDRs. We are additionally concerned about stated capabilities of QCDRs. If a vendor or entity has been qualified by CMS as a QCDR or qualified registry, but then is found to be unable to fulfill reporting requirements for which it had been qualified, eligible clinician participants of the QCDR or qualified registry should not be penalized for their inability to report performance data. The AAFP believes language must be included within the final rule that explicitly holds harmless any eligible participants of QCDRs and qualified registries under these circumstances.

While the opportunity to earn bonus points is appealing, the current proposal for bonus points is not meaningful or helpful, and demonstrates the unnecessary complexity and burden within the proposed rule. Currently, bonus points are tied to adoption and integration of technology into a practice, with additionally complex and burdensome requirements. Successfully navigating the challenges required to earn a bonus point then would result in the bonus point becoming a fraction of a fraction of points which then becomes a percentage within the overall score. The potential bonus point becomes so diluted it does little to motivate eligible clinicians to invest the energy or resources required to earn the fraction of the fraction of a percentage attributed to the bonus point; therefore, it just adds complexity. Therefore, the AAFP does not support the bonus points at this time.

(3) Submission Deadlines:
For QCDR, CEHRT, Qualified Registry, and attestation submission, CMS proposes the data submission period would begin January 2 following the close of the performance period. For example, for the first MIPS performance period, the data submission period would occur from January 2, 2018, through March 31, 2018. CMS seeks comment on whether a shorter time frame would be advantageous, whether submission throughout the performance period (e.g., biannual or semiannual) would be preferable, and whether to include January 1.

CMS also seeks comment on the period for the Medicare Part B claims submission mechanism being January 1 through March 31 and whether the period for the CMS Web Interface

submission mechanism should be eight weeks starting after January 1 and ending no later than March 31.

AAFP Response
We call for the period for data submission to be at least 90 days. The AAFP believes that a shorter time frame and submission deadline earlier than March 31st could be difficult for many eligible clinicians. Given that clinicians employed by health systems may not receive or have access to December data until February and cumulative year-to-date data following that, establishing an earlier submission deadline could result in clinicians being unable to meet the requirements. This could be extremely detrimental to clinicians' scoring and reimbursements, and penalize clinicians for lack of timely data availability and submission which is beyond their control.

The opportunity to submit throughout the performance period would be advantageous to some practices, but should not be required. Since all practices operate differently, some would find value in a one-time submission while others would appreciate multiple submission opportunities.

Simplification and standardization of submission periods, irrespective of submission mechanism, is recommended. To decrease confusion for MIPS-eligible clinicians as well as for CMS, the AAFP sees an advantage in aligning submission timeframes and setting the same end-date for all submission mechanisms. We suggest that all submission periods run from January 1 through March 31.

b. Quality Performance Category
CMS proposes that for the 2019 MIPS adjustment year, the Quality performance category will account for 50 percent of the CPS, subject to the Secretary's authority to assign different scoring weights under section 1848(q)(5)(F) of the Act. MIPS-eligible clinicians who fail to report on a required measure or activity will receive the lowest potential score applicable to the measure or activity. CMS proposes that MIPS-eligible clinicians must report six measures including one cross-cutting and one outcomes measure. If an outcome measure does not exist for any given sub-specialty, they can then report a high-priority measure. In addition, CMS asks if MIPS-eligible clinicians should be able to select from all measures or from the specialty-specific list. CMS seeks comments on the appropriateness of measures included in the specialty-specific measure set.

AAFP Response
The AAFP supports reasonable and achievable programs that promote continuous quality improvement and that measure patient experiences. The AAFP opposes an approach that requires physicians to report on a complex set of measures that do not impact or influence the quality of care provided to patients.

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. To accomplish this, 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 also supports reducing health disparities as a part of care delivery and urges CMS to move forward with expanding its risk-adjustment methodology in quality measures to incorporate social and economic factors such as race, income, education, and region. Risk-

adjusting for socioeconomic status ensures the measures are fair and sets the standard for comparison of physician performance by adjusting for factors outside of the physician's control. Not adjusting could lead to misleading conclusions about physician performance. As a result, further disparities in care could be magnified.

We support the reduction of measures to six including one cross-cutting and one outcome measure. We support scoring measures individually so as to avoid an "all or none" approach (e.g., if a physician successfully reports only 5 measures, the physician could still be awarded partial credit for the Quality Performance category.)

Measures that should be added to the Family Medicine set (these measures might be in other tables/lists, but need to be included in the Family Medicine set for simplicity and they should be called the Primary Care Core Measures):

- 0018- Controlling HTN. This measure is listed as a MIPS cross-cutting measure which is appropriate. It is also a CQMC Primary Care set measure and should be included in the MIPS Family Medicine measure set. This is the only one that is on the PQRS and Core Quality Measure Collaborative (CQMC) Core Measure set and did not make it onto the Family Medicine measure set.
- 0071- Persistent Beta Blocker Treatment after a Heart Attack. This is listed as a proposed new measure for MIPS. This measure is in the CQMC Primary Care Core set and should be in the MIPS Family Medicine set.
- 0068- Ischemic Vascular Disease: Use of Aspirin or other Antiplatelet. This measure is in the MIPS Internal Medicine set and is the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set.
- 0056-Comprehensive Diabetes Care: Foot Exam. This measure is in the MIPS Internal Medicine set and is the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set.
- 0057- Comprehensive Diabetes Care: HbA1c Testing. This measure is not currently included in MIPS. It is in the CQMC Primary Care set and should be included in the MIPS Family Medicine measure set.
- 0062- Comprehensive Diabetes Care: Urine Protein Screening. This measure is currently included in MIPS as Measures Proposed with Substantive Changes (Appendix Table G). It is in the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set.
- 0097- Medication Reconciliation. This measure is currently included in MIPS as Measures Proposed with Substantive Changes (Appendix Table G). It is in the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set as well as the cross-cutting set for MIPS.
- 0032- Cervical Cancer Screening. This measure is currently included in MIPS as Measures Proposed with Substantive Changes (Appendix Table G). It is in the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set.
- 0028- Preventative Care Screening: Tobacco Use: Screening and Cessation. This measure is listed as a cross-cutting measure which is appropriate. It is also a CQMC Primary Care set measure and should be included in the MIPS Family Medicine measure set.
- 0421- Preventative Care Screening: BMI Screening and Follow Up. This measure is listed as a cross-cutting measure which is appropriate. It is also a CQMC Primary Care set measure and should be included in the MIPS Family Medicine measure set.

- 0005- CAHPS. This measure is listed as a cross-cutting measure which is appropriate. It is also a CQMC Primary Care Set measure and should be included in the MIPS Family Medicine measure set.
- 0710- Depression Remission at 12 months. This measure is currently included in MIPS as Measures Proposed with Substantive Changes (Appendix Table G). It is in the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set.
- 1885- Depression Response at 12 months-Progress towards remission. This measure is not currently included in MIPS. It is in the CQMC Primary Care set and should be included in the MIPS Family Medicine measure set.
- 1799- Medication Management for People with Asthma. This was listed as a proposed new measure for MIPS (Appendix Table G). This measure is in the CQMC Primary Care Core set and should be in the MIPS Family Medicine measure set.
- N/A- Non-recommended Cervical Cancer Screening in Adolescent Females: This measure is in the MIPS OB/GYN set and is the CQMC Primary Care set and should be added to the MIPS Family Medicine measure set.

The following measures are currently listed in the MIPS family medicine measure set. These all are also in the CQMC Primary Care Core set. The AAFP supports this alignment.

- 0059- Comprehensive Diabetes Care: HbA1c Poor Control (> 9.0 percent)
- 0055- Comprehensive Diabetes Care: Eye Exam
- 2372- Breast Cancer Screening
- 0034- Colorectal Cancer Screening
- 0052- Use of Imaging Studies for Low Back Pain
- 0058- Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

The AAFP strongly calls for specialists and sub-specialists to be required to meet the same program expectations as other MIPS participants. The current requirement is 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 particular specialty groups in MIPS, that lower number of measures for reporting should be available to all MIPS-eligible clinicians. If specialists and sub-specialists do not report on six measures, they should get a score of zero for the measures that are not reported.

We believe that parity in reporting across all physician groups is critically important. Reducing what seem to be reasonable/achievable requirements for some specialties will result in a continued disproportionate burden on those specialties that have been engaged in quality measurement and development. Parity in reporting requirements could also spur the development of meaningful quality measures in areas that may currently be lagging. We encourage CMS set the reporting bar for all specialties, rather than lowering it for selected ones.

The proposed rule discusses the belief that outcome measures are more valuable, that the agency may increase the number of outcome measures required over the next few years, and that high-priority measures (outcome, appropriate use, patient safety, efficiency, patient experience, and care coordination) are more important, while the number required for these also may increase. As such new and better measures are added, then others should be removed so that the total number remains parsimonious. The AAFP supports the use of these measures which are the overuse measures included in the Primary Care Core measure set:

- 0058- Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis;
- 0052- Use of Imaging Studies for Low Back Pain; and
- N/A- Non-recommended Cervical Cancer Screening

CMS also seeks input on ways to minimize potential gaming (e.g., if a MIPS-eligible clinician only reports on measures that do not meet the minimum sample size, the measure is not counted and not scored zero, and therefore decreases the weight of their overall quality score). As previously called for, the AAFP urges CMS to require that all MIPS-eligible clinicians report on six measures. These measures should all have a minimum sample size of 20 patients. MIPS-eligible clinicians should be required to pick only measures that fulfill this sample size requirement. If needed, cross-cutting measures can be used to complete the set of six measures

(ii) Submission Criteria for Quality Measures for Groups Reporting via the CMS Web Interface
For groups of 25 or more MIPS-eligible clinicians who want to report via the CMS Web Interface, CMS proposes they must report on all measures included in the CMS Web Interface completely, accurately, and timely by populating the field for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order they appear. If less than 248, then they must report on 100 percent of who is listed. Any measure not reported gets a score of zero. If there are no assigned patients, the practice must then use another method to submit data.

The VM uses an attribution method that attributes the beneficiary to the TIN that bills the plurality of primary care services. For CMS Web Interface attribution, this program would be similar, but would update the definition of primary care and attribute to different identifiers used in MIPS.

AAFP Response
It is critical that Quality and Resource Use measurement be coupled with adequate and useful reports for clinicians—they need timely and actionable clinical and claims data to make value-based care decisions both for their practice as well as for those to whom they refer.

(iii) Performance Criteria for Those Electing to Report CAHPS
CMS proposes to allow groups of two or more MIPS-eligible clinicians to report voluntarily CAHPS for MIPS. It would count as a cross-cutting or patient experience measure. A group may report any five measures, plus CAHPS, to achieve the six-measure threshold. The group would bear the cost of the survey, but also receive bonus points for reporting CAHPS. CMS seeks comments on whether reporting through CAHPS be required and not voluntary for groups of 100 or more.

AAFP Response
The AAFP believes that practices should not be required to pay to participate in a federal program. For this reason, the use of CAHPS should be optional for all practices, even groups of 100 or more until such time it or a similar product is made available without cost.

(b) Data Completeness Criteria
CMS seeks feedback on a proposal to increase the percentage of patients to be reported by each mechanism when compared to PQRS.

The proposed rule also discusses that in some circumstances (e.g., telehealth, certain acute situations) it may not be appropriate to report a cross cutting measure and the percentage may need to be lower.

AAFP Response
Given the difficulty most physicians experienced reporting PQRS, we recommend that CMS start the MIPS program with data thresholds at the same level or lower than those required for PQRS reporting. Expanding reporting to all payers for qualified registries will significantly increase the number of patients reported. Further increasing the threshold to 90 percent (from 50 percent) may make it very difficult for most providers to reach the threshold. Qualified registry reporting continues to involve manual steps to identify measures that are applicable and to retrieve and report all data elements needed for selected measures.

For example, clinicians who do not have an EHR (or that have an EHR, but are not capturing all data in structured fields) may use billing files to identify eligible patients for specific measures. However, billing data does not capture all data elements such as medications, vitals, hospitalizations, colonoscopies, and mammograms. That data must often be collected and reported using manual abstraction. The increased thresholds would be extremely burdensome and expensive to report.

Regarding situations where reporting a cross-cutting measure might not be appropriate, exclusions need to be built into the measures themselves to fully avoid reporting quality measures on such patients. Measure developers and stewards need to be educated about these possible exclusions moving forward.

(4) Application of Quality Measures to Non-Patient Facing MIPS-Eligible Clinicians
MACRA stipulates that CMS must give consideration to the circumstances of non-patient-facing MIPS-eligible clinicians and may, to the extent feasible and appropriate, take those circumstances into account and apply alternative measures or activities that fulfill the goals of the applicable performance category to such clinicians.

AAFP Response
The AAFP opposes re-weighting the Quality category to zero. Instead we propose that if there are not six measures available in a specialty set, the eligible clinician needs to choose measures from the cross-cutting set to fill out the remaining measures.

(5) Global and Population Based Measures
MACRA allows CMS to use global outcomes measures and population-based measures for the quality performance category. CMS proposes to use the acute and chronic composite measures of the AHRQ's Prevention Quality Indicators that meet a minimum sample size (20) in the calculation of the quality measure domain. MIPS-eligible clinicians will be measured on these as well as the six performance measures. In addition, CMS proposes to include the all-cause hospital readmission measure from the VM. For solo clinicians or practices with fewer than 10 clinicians, this additional measure does not apply. CMS seeks comments on what additional measures could be added for future use.

AAFP Response
The AAFP recognizes the current use of measures like the all-cause readmission measure in VM. However, in our experience with physicians, interaction with and understanding of the VM program and the resultant QRURs are low. The EIDM registration is cumbersome and time-

consuming to complete (often taking several weeks to receive approval) and required roles are not obvious, the current portal is not intuitive to navigate, reports take a significant time to download, and once downloaded, are difficult and time-consuming to interpret. We propose a phased-in approach for population-based and global outcome measures in which the MIPS program would begin with the six measures (including one cross-cutting and one outcome based) for scoring. We believe that population-based measures should be tested in the program before composite performance scores are based on their results. For the first two years, CMS needs to collect and disseminate data to eligible clinicians on global outcome and population-based measures so they can learn about measurement at a population level and CMS can learn how population level measurement will impact the MIPS program.

c. Selection of Quality Measure for Individual MIPS-Eligible Clinicians and Groups
(1) Annual List of Quality Measures Available for MIPS Assessment
CMS proposes to publish an annual list of quality measures in the *Federal Register* no later than November 1 of the year prior to the first day of the performance period and that CMS will solicit a "call for measures" each year. CMS will request that eligible clinician organizations and other stakeholders submit measures and updates. The agency proposes that only measures submitted before June 1 of each year will be considered in the annual list of quality measures for the performance period beginning 2 years after the measure is submitted. CMS seeks comment on whether there are measures that should be classified in a different National Quality Strategy domain or classified as a different type (process vs. outcome, etc.).

AAFP Response
As the proposed rule is currently written, there is a 30-month gap between when measures are submitted and when they are used. As a participant in the CQMC and Measure Application Partnership (MAP), the AAFP understands and supports multi-stakeholder input into measure selection for federal programs. However, the current process keeps new knowledge sequestered from measurement and patient benefit until the measure update process can be completed. Also, multi-stakeholder time and resources were invested in the CQMC development of Core Measure sets. These sets need immediate integration into the final rule with a strong message sent to private payers to adopt the sets for private programs in order to reduce measurement burden on physicians and improve the quality of care for patients.

(2) Call for Quality Measures
The proposed rule discusses how and when they submit measures for MIPS. Stakeholders should consider measures that are:

- Not duplicative of an existing or proposed measure;
- Beyond concept phase and have at least begun testing;
- Inclusive of data submission beyond claims;
- Based on outcomes'
- Address patient safety and adverse events;
- Identifying appropriate use of care;
- Address care coordination;
- Pertain to patient and caregiver experience;
- Identify cost and Resource Use; and
- Attempt to address a performance gap.

AAFP Response
As measures are considered for MIPS, the AAFP points out that outcome measures are an end point and not a starting point. Establishing strong and meaningful process measures that are tied to evidence-based outcomes can help lead a practice toward improvement. Disjointed process and outcome measures lead to an increased administrative burden with very little quality improvement.

(3) Requirements
MACRA requires that, in selecting quality measures for inclusion in the annual final list of quality measures, CMS must assure, to the extent practicable, that all quality domains are addressed by such measures. The regulation discusses how the agency has found the NQF convened Measure Application Partnership's (MAP) input valuable and proposes to consider the MAP's recommendations as part of the comprehensive assessment of each measure considered for inclusion under MIPS. In addition, CMS proposes to consider measures that fill clinical gaps, changes or updates to performance guidelines, and other program needs.

AAFP Response
The AAFP supports the use of the MAP as a way to assess measures for inclusion in MIPS. We encourage a continued look at ways to streamline the National Quality Forum's processes to allow for more rapid updates to measures as new clinical guidelines emerge.

7. Exception for Existing Quality Measures (and)
8. Consultation with Relevant Eligible Clinician Organizations and Other Relevant Stakeholders
In these two sections, CMS proposes that measures in the current VM and PQRS will be included in the MIPS measures list unless removed by the Secretary. CMS also discusses the importance of the MAP and CQMC.

AAFP Response
The AAFP supports the core measure sets developed by the multi-stakeholder Core Quality Measures Collaborative that were developed to ensure alignment, harmonization, and the avoidance of competing quality measures among all payers and encourages CMS to continue to engage with this group as well as the MAP. The AAFP supports inclusion of all core measures in the existing or proposed measures under MIPS and with current and future attention to such sets remaining parsimonious in number of total measures in each set.

9. Cross-Cutting Measures for 2017 and Beyond
In this section, CMS discusses the importance of cross-cutting measures indicating that several are being removed from the PQRS cross-cutting measure list, but will still be included in the regular MIPS list.

AAFP Response
MIPS-eligible clinicians must report on six measures, which include one cross-cutting measure and one outcomes measure. Cross-cutting measures help focus efforts on population health and allow for meaningful comparison among MIPS-eligible clinicians. The MIPS cross-cutting list is based on the cross-cutting measures from PQRS, but some will be eliminated in an effort to make the list applicable to all patient-facing clinicians. <u>The AAFP suggests that the following measures found currently in PQRS, but proposed to be removed from the cross-cutting measures list, remain in the list to make it more robust:</u>

- 046 Medication Reconciliation Post Discharge

- 110 Preventative Care and Screening: Influenza Immunization
- 111 Pneumonia Vaccination Status for Older Adults
- 112 Breast Cancer Screening
- 131 Pain Assessment and Follow Up
- 134 Preventative Care and Screening: Screening for Clinical Depression and Follow-Up Plan
- 154 Falls: Risk Assessment
- 155 Falls: Plan of Care
- 182 Functional Outcome Assessment
- 318 Falls: Screening for Falls Risk

e. Resource Use Performance Category
(1.a) General Overview and Strategy
CMS envisions the measures in the MIPS Resource Use performance category would provide MIPS-eligible clinicians with the information they need to provide appropriate care to their patients and enhance health outcomes.

AAFP Response
The AAFP applauds this CMS sentiment, but the proposed rule is not at all clear on how CMS will provide clinicians with timely and actionable feedback on their Medicare Resource Use performance. It is critical that Resource Use measurement be coupled with adequate and useful feedback reports for clinicians, all of whom need timely and actionable clinical and claims data to make value-based care decisions both for their practice as well as for those to whom they refer. Furthermore, family physicians and other clinicians need the data seamlessly integrated into their workflow. For example, a system to flag duplicative tests or procedures that are susceptible to overuse presents a mutually beneficial opportunity to engage with clinicians on the practice profiles and patient populations who are most likely to benefit from the test or service ordered. The AAFP believes payer-clinician engagement is equally, if not more important than Resource Use measurement in effecting change.

The AAFP opposes application of the total per capita cost of care measure to primary care physicians that are not part of an advanced APM. 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 can not 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.

Also, patient choice, adherence, and accountability affect the total per capita cost of care and should be quantified and factored into Resource Use calculations. Depending on a Medicare beneficiary's supplemental insurance coverage, patients are able to choose which services to utilize even if their family physician does not recommend those services. In addition, patients in fee-for-service Medicare may choose to see any provider they wish including specialists, whether or not they are referred by a primary care provider. Physician accountability for costs needs to be balanced with patient accountability.

Finally in regards to total per-capita cost of care, primary care physicians refer to specialists when a greater depth of knowledge is needed and rely on the professional opinion and recommendations of the specialist to determine the best course of care. If the specialist in combination with the patient determines that certain tests and procedures are needed, the primary care physician is not in a position to question those decisions nor their associated costs. Most times these tests are completed before the primary care physician is aware they were even ordered. The total cost of care measure holds providers accountable for costs they do not control. We support focusing solely on episode-based care in the Resource Use section and eliminating total cost of care.

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 groups as the sole method of measuring Resource Use in order 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 this proposed rule as a plurality of claims, rather than the methodology suggested in this proposed rule.

(2) Weighting the CPS
As required by MACRA, the Resource Use performance category shall make up no more than 10 percent of the CPS for the first MIPS payment year and not more than 15 percent of the CPS the second MIPS payment year. Starting with the third MIPS payment year and for each MIPS payment year thereafter, the Resource Use performance category would make up 30 percent of the CPS.

CMS also will closely examine the recommendations from HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) study, once they are available, on the issue of risk adjustment for socioeconomic status on quality measures and Resource Use.

AAFP Response
The AAFP adamantly urges CMS to make timely and actionable data available as Resource Use weighting increases significantly as a proportion of the CPS from 2019 to 2021. As clinicians are held increasingly accountable for costs during the first three years of MIPS, thereby increasing their downside risk, clinicians deserve an increasingly robust and reliable cost forecasting and reporting tool to offset that risk. It is only fair to provide needed tools to clinicians as the weighting of this Resource Use within CPS increases. In addition, the AAFP believes attribution logic and risk adjustment methodologies need to improve continually as Resource Use becomes a larger component of the CPS. It will be imperative that clinicians can reconcile any issues with patient attribution and the attribution needs to be available to the physician no less frequently than quarterly.

The AAFP recommends CMS quickly analyze the ASPE study results to determine how best to apply socioeconomics and social determinants of health into risk adjustment for quality and Resource Use measures. The AAFP believes socioeconomics and social determinants of health factor into improving risk adjustment, chronic disease management, and achieving positive clinical outcomes.

(3) Resource Use Criteria
CMS proposes that each individual MIPS-eligible clinician's and group's Resource Use performance be calculated using administrative claims data.

AAFP Response
We support the use of the administrative claims data for calculating Resource Use.

(a) Value Modifier Cost Measures Proposed for the MIPS Resource Use Performance Category
CMS proposes to include the total per-capita cost measure during the performance period and to adopt the Medicare Spending per Beneficiary (MSPB) by the beginning of the initial MIPS performance period in 2017.

AAFP Response
CMS states, "We anticipate that MIPS-eligible clinicians are familiar with the total per capita cost measures as the measure has been reported through the annual QRUR to all groups starting in 2014." This statement is in contradiction to information obtained from AAFP members. First, the report poses a challenge to access, let alone the time needed to interpret the data. It is the AAFP's recommendation that all clinicians have access to feedback reports personally rather than having to rely on an administrative security official to access and share reports. CMS also must simplify the process by which a clinician gains access since physicians indicate that the EIDM registration is cumbersome and time consuming to complete (often taking several weeks to receive approval). Required roles are not obvious, the current portal is not intuitive to navigate, reports take a significant time to download, and once downloaded, are difficult to interpret.

Secondly, since both total per capita cost and MSPB measures were created for hospital comparisons, the AAFP urges CMS to remove these measures from the MIPS Resource Use category.

The AAFP believes that CMS should use care episode group measures as the only measures to calculate Resource Use at this time. Episode-based groups will bring emphasis to high volume and high cost conditions and procedures giving providers the information they need to change their Resource Use.

The AAFP appreciates CMS using CMS-HCC to adjust for patient risk. We encourage CMS to continuously update and evaluate this model. Family physicians need to understand how ICD-10 coding will affect risk adjustment and payment. Enhanced education from CMS is needed for family physicians to understand the concepts in HCC and how it will impact quality and Resource Use comparisons, and ultimately, payment adjustments.

(i) Attribution
For the MSPB measure, CMS proposes to use attribution logic whereby MIPS-eligible clinicians with the plurality of claims for Medicare Part B services rendered during an inpatient hospitalization would be assigned the episode.

For the total per capita cost measure, CMS proposes to use a two-step attribution methodology that is similar to the methodology used in the 2017 and 2018 VM**.**

AAFP Response
Since the AAFP opposes total per capita cost and MSPB measures within MIPS, AAFP will not respond to how to attribute patients for those measures.

The AAFP's position regarding any attribution model is that patients must be attributed based on who can control those specific costs. The model must include a reconciliation process for clinicians to review, add, or remove patients from the list received by CMS. The AAFP has heard from many of its members that there is little recourse or opportunity to make corrections to their list of attributed patients. The AAFP feels that inclusion of a reconciliation process would help alleviate this problem.

(ii) Reliability (Value Modifier Cost Measures Proposed for the MIPS Resource Use Performance Category)

In the 2013 final Medicare physician fee schedule, in the discussion of reliability for the cost and quality measures being selected for the physician value-based payment modifier, CMS stated:

> *We believe it is crucial that the value-based payment modifier be based on quality of care and cost composites that reliably measure performance. Statistical reliability is defined as the extent to which variation in the measure's performance rate is due to variation in the quality (or cost) furnished by the physicians (or group of physicians) rather than random variation due to the sample of cases observed. Potential reliability values range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rate is the result of variation in differences in performance across physicians (or groups of physicians). Generally, reliabilities in the 0.40–0.70 range are often considered moderate and values greater than 0.70 high.*

In the MACRA proposed rule, CMS proposes to use a 0.4 reliability threshold for evaluating the inclusion of a Resource Use measure in the MIPS composite performance score.

AAFP Response
This proposal seems inconsistent with what commercial health plans and professional statisticians consider to be the minimum reliability threshold for a physician cost profiling measure: 0.7 as published in the *New England Journal of Medicine*. Two studies, "The Reliability of Physician Cost Profiling in Medicare," a study conducted by staff from Thomson Reuters for the Medicare Payment Advisory Commission, and "Benchmarking Physician Performance: Reliability of Individual and Composite Measures" published in the *American Journal of Managed Care* indicated that composite measures are only reliable and valid at the 0.7 confidence level. The AAFP urges CMS to use a 0.7 reliability threshold instead of the proposed 0.4 threshold. Using a 0.4 threshold effectively means that, on average, a clinician's observed Resource Use performance is more likely to be the result of statistical error (or random variation) in the measurement of performance, rather than an accurate measurement of actual Resource Use. Implementing the proposed reliability threshold would severely undermine clinicians' confidence in the MIPS Resource Use measures and could limit the usefulness of Resource Use feedback reports from CMS to providers, because they will, correctly, doubt how accurate they are.

The AAFP agrees with CMS that specialty adjustment for Resource Use measures is not needed, particularly if total per capita cost and MSPB measures are eliminated and patients are attributed to episode groups based on highest Part B allowable costs. Since episode groups are

tied to specific clinical conditions and treatments, the AAFP agrees with CMS that additional adjustment for physician specialty is redundant.

CMS also proposes to make a second technical change to the MSPB measure's calculation. They propose to modify the cost ratio used within the MSPB equation to evaluate the difference between observed and expected episode cost at the episode level before comparing the two at the individual or group level.

The AAFP again urges CMS to only use episode-based groups to calculate Resource Use at this time and eliminate the MSPB measure.

(b) Episode-based Measures Proposed for the MIPS Resource Use Performance Category
CMS is considering 41 clinical condition and treatment episode-based measures to use within the Resource Use performance category for the first MIPS performance period.

AAFP Response
The AAFP encourages CMS to include all measures to monitor and reduce cost thereby capturing a wide array of specialists and the largest number of Medicare eligible clinicians. This will help Medicare more quickly bend the cost curve.

In the case of the episode-based measures, patients should be attributed to the physician who bills the largest portion of Part B allowable charges for clinical condition and treatment episodes, instead of what is proposed. We believe that assigning attribution based on number of visits [i.e. inpatient evaluation and management (IP E&M)] would disproportionally hold the primary care physician responsible for the Resource Use of the specialist. Some of the proposed clinical conditions and treatment episode-based measures may be influenced by primary care, while others are outside of their control. Theoretically, an integrated health care system could manage costs through all settings for the episode. However, that would not be true of small and independent practices or those in rural areas. The proposed clinical and treatment episode-based measures may pose significant unintended consequences if the costs are not accurately attributed to the physician with the highest cost.

While CMS has defined the triggering claim for each episode, family physicians and other clinicians need additional information to understand the total scope and cost of each episode. For example, they need to know for each episode:

- The desired clinical outcome;
- The services and costs to be included and excluded;
- The endpoint;
- The network of appropriate/expected clinicians delivering care;
- Whether performance reports will have information about their own performance as well as other clinicians; and
- Whether information contained in reports will enable them to determine the underlying cause of performance deficiencies.

With this additional information, clinicians can begin to understand if, when, and how an episode will affect their Resource Use performance.

Cost measurement is one of the two variables used to measure value. The other is quality/outcomes. The AAFP strongly urges CMS to include within each clinical condition and

treatment episode the data on costs/utilization and quality/outcomes. This would require the identification of specific outcomes related to the condition or service being measured, rather than some general measure, such as all cause readmissions. If CMS properly selects and designs Resource Use measures tied to episodes of care and provides timely and actionable data, it has an opportunity to impact costs, care improvement activities and physician behavior. Lastly, syncing data on costs/utilization and quality/outcomes will create an opportunity to improve risk adjustment and attribution methodologies to the individual clinical condition or treatment being measured.

(i) Attribution
For acute condition episodes, CMS proposes to attribute those episodes to MIPS-eligible clinicians that bill at least 30 percent of IP E&M visits during the initial treatment, or "trigger event," that opened the episode. In addition, for procedural condition episodes, CMS proposes to attribute those episodes to MIPS-eligible clinicians who bill a Medicare Part B claim with a trigger code during the trigger event of the episode. Since it is possible for more than one MIPS-eligible clinician to be attributed to a single episode using either rule, will CMS then split the Resource Use measures among attributed clinicians, based on the care they deliver?

AAFP Response
The AAFP believes patients should be attributed to the physician who bills the largest portion of Part B allowable charges, as defined by CMS in this proposed rule as plurality of claims, for acute condition and treatment episodes instead of what is proposed. We believe that assigning attribution based on number of visits does not attribute patients to the physician that can make the biggest impact on reducing costs and would disproportionally hold the primary care physician responsible for the Resource Use of the specialist.

(ii) Reliability
CMS proposes to use the minimum of 20 cases for all episode-based measures listed in Tables 4 and 5.

AAFP Response
The AAFP urges CMS to use a minimum reliability threshold of 0.7 for all resource use measures used in MIPS. The minimum number of cases needed to achieve a reliability threshold of at least 0.7 will vary for each of the episode-based measures based on each measure's statistical characteristics. Thus, CMS should determine the minimum number of cases separately for each measure such that each achieves at least 0.7 reliability.

(4) Future Modifications to Resource Use Performance Category
In the future, CMS intends to consider how best to incorporate Part D costs into the Resource Use performance category.

AAFP Response
We urge CMS to review the AAFP's letter sent to CMS on May 9, 2016, in regards to the proposed rule titled, "Medicare Program; Part B Drug Payment Model." In the letter, the AAFP applauded the agency's efforts to apply common sense, value-based payment (VBP) principles to the delivery of physician-administered pharmaceutical and biologic treatments. Much of the information contained in that letter describes how to best control the costs of drugs by focusing on measuring its performance.

In the Medicare Program Part B Drug Payment Model, CMS proposed to use a value-based pricing strategy that would vary prices for a given drug based on its clinical effectiveness for different indications that are covered under Medicare (also known as indications-based pricing). The AAFP believes value-based or, in this case, indications-based pricing of drugs should take a balanced approach using factors such as research and development costs, clinical outcomes/efficacy, clinical comparability, side effects, safety, patient adherence, and ease of use for the patient. In addition, this approach should not create separate pay-for-value structures for each drug, but rather a practical, pay-for-value structure for most drugs. The AAFP offers this basic framework for value-based pricing of prescription drugs:

- A drug with proven, positive clinical outcomes has value.
- A drug without proven, positive clinical outcomes does not have value.
- A high-cost drug still has value if it improves a patient's health and reduces spending on other forms of health care.
- If a new, more expensive drug has the same clinical outcome as an older, less expensive drug, the new, more expensive drug has less value.

Also in the Medicare Program Part B Drug Payment Model, in regards to outcomes-based, risk-sharing agreements, CMS proposed that pharmaceutical manufacturers provide performance measures to determine the clinical value for a specific drug in outcomes-based, risk-sharing agreement. The AAFP believes this proposal should include details about the scope of CMS' authority; a clearly defined objective; and the mechanism for negotiating outcomes-based, risk-sharing agreements. CMS needs to specify several important considerations, such as what is being negotiated, (prices, formulary placement, or both), and what to do if the negotiating parties are unable to come to agreement. A pricing framework, similar to the one offered above, to guide arbitration in determining the price of drugs is also needed to capture the relevant factors that would be considered in determining the appropriate price for a drug.

In the Medicare Program Part B Drug Payment Model, CMS proposed to implement a clinical decision support (CDS) tool for physicians prescribing appropriate drugs. The tool would have two components consisting of an online interface that supports clinical decisions through education and a feedback mechanism based on drug utilization in Medicare. The AAFP applauds CMS for developing and implementing such a tool. Physicians need the drug performance data to make informed, value-based decisions on prescribing drugs, along with evaluating and managing therapies. The AAFP policy on "Patient-Centered Formularies" states, "Health plans and [pharmacy benefit managers] should provide drug utilization and cost information to physicians in clear and understandable reports that are useful for physicians in affecting positive change in their prescribing behavior." As value-based arrangements tie payment to physicians' performance, physicians' performance will then be bound to prescription drug performance. Therefore, family physicians and other primary care providers need clear, real-time, patient-specific information to make the best care decisions for their patients. Clinical and cost information on drugs should include:

- Clinical outcomes
- Drug interaction and allergy alerts, along with clinical support guidelines
- The patient's demographic information
- The patient's prescription drug benefit coverage
- The out-of-pocket costs the patient will incur at any given pharmacy for prescribed medications (along with alternative pharmacy options)
- Alternative drug therapies for a physician's consideration

The AAFP believes CDS tools should help physicians and their care teams proactively identify diagnostic options; the best treatment options; early warnings of potential problems; and alternative treatments for the physician, care team, and patient to consider. The CDS tool should contain drug information based on evidence-based, up-to-date, and scientific/medical evidence. It should include a mixture of clinical information, such as updated guidelines for the clinical use of drugs, updated safety information, and processed patient data that takes into account their experiences and outcomes. Only with this complete data set will the CDS tool enable physicians to ensure the correct drug dosing; reduce the risk of toxic drug levels; reduce the time to achieve therapeutic drug levels; decrease medication errors; and change prescribing patterns in accordance with evidence-based clinical guidelines. Without the free flow of bi-directional information from all stakeholders working together to improve quality and reduce overall cost, value-based health care will never materialize.

Finally, the AAFP also supports reducing health disparities as a part of care delivery and urges CMS to move forward with expanding its risk-adjustment methodology in Resource Use measures to incorporate social and economic factors such as race, income, education, and geographic region. Risk-adjusting for socioeconomic status ensures the measures are fair and sets the standard for comparison of physician performance by adjusting for factors outside of the physician's control. Not adjusting could lead to misleading conclusions about physician performance. As a result, further disparities in care could be magnified.

f. CPIA Category
CMS proposes that CPIA account for 15 percent of the CPS and that certified patient-centered medical homes (PCMHs) receive the highest potential score. Eligible clinicians or groups who are participating in an APM will earn half of the CPIA points. MIPS-eligible clinicians or groups that fail to report on applicable measures or activities that are required to be reported, will receive the lowest potential score applicable to the measure or activity.

CMS also proposes that PCMH will be recognized if it is a nationally recognized accredited PCMH, a Medicaid medical home model, or a medical home model. The NCQA Patient-Centered Specialty Recognition will also be recognized. Nationally recognized accredited PCMHs are recognized if they are accredited by the:

- Accreditation Association for Ambulatory Health Care;
- The National Committee for Quality Assurance (NCQA) PCMH recognition;
- The Joint Commission Designation; or
- The Utilization Review Accreditation Commission (URAC).

The criteria for being a nationally recognized PCMH are that it must be national in scope and must have evidence of being used by a large number of medical organizations as the model for PCMH.

AAFP Response
The AAFP believes strongly 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 PCMH. In addition, the PCMH recognition or certification of a practice by an accrediting body may not accurately capture actual advanced primary care functionality.

Therefore 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 Patient-Centered Medical Home (PCMH) and the five key functions of the Comprehensive Primary Care (CPC) Initiative. These key functions are:

1. Access and Continuity: PCMH practices optimize continuity and timely, 24/7 access to care supported by the medical record. Practices track continuity of care by physician or panel.
2. Planned Care for Chronic Conditions and Preventive Care: PCMH practices proactively assess their patients to determine their needs and provide appropriate and timely chronic and preventive care, including medication management and review. Physicians develop a personalized plan of care for high-risk patients and use team-based approaches to meet patient needs efficiently.
3. Risk-Stratified Care Management: Patients with serious or multiple medical conditions need extra support to ensure they are getting the medical care and/or medications they need. PCMH practices empanel and risk stratify their whole practice population and implement care management for patients with high needs.
4. Patient and Caregiver Engagement: PCMH practices engage patients and their families in decision-making in all aspects of care. Such practices also integrate into their usual care both culturally competent, self-management support and the use of decision aids for preference sensitive conditions.
5. Coordination of Care Across the Medical Neighborhood: Primary care is the first point of contact for many patients and leads in the coordination of care as the center of patients' experiences with health care. PCMH practices work closely with patients' other health care providers to coordinate and manage care transitions, referrals, and information exchange

The AAFP considers these five key functions equally important for the delivery of advanced primary care. These functions depend on the support of enhanced accountable payment, continuous quality improvement driven by data, and optimal use of health information technology, including a certified electronic health record with a data registry or repository capability. In addition, in an advanced primary care practice, such as a PCMH, the use of annual milestones should guide the development of these five functions and build the capability to deliver them.

The AAFP supports attestation as the method for recognizing whether a practice meets the threshold requirements for a PCMH. A practice would attest to achievement of milestones, similar to those used in the original CPC Initiative. The reporting would be on a quarterly to annual basis, depending on the particular milestones being reported and the evolution of the practice. Practices that are more advanced may have fewer reporting requirements than those at earlier stages on the transformation continuum. The quality, patient experience, and utilization data that practices report will serve to validate whether a practice is delivering what it attests.

The AAFP suggests CMS use a deeming authority to grant any entity which meets the necessary criteria as a PCMH accreditor to be an approved program. 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. The four groups developed and adopted the principles in March 2007. CMS could use these guidelines in exercising such a deeming authority. In addition, the AAFP encourages the inclusion of state-based, payer-sponsored, or regional PCMH recognition programs.

Regarding the specialty designation of medical homes, NCQA is the only program that currently offers specialty recognition. The standards for specialty medical home certification under the 2016 NCQA Patient-Centered Specialty Practice (PCSP) program align much more closely with the PCMH standards than in the past. While these standards call for expanded coordination and collaboration with primary care, we believe a specialty medical home designation alone, in the absence of a primary care PCMH, is not sufficient to warrant special treatment under MIPS. Specialty practices support and complement a primary care patient-centered medical home, but do not replicate all aspects of PCMH, and do no replace the need for a primary care medical home. We also are concerned that only one such specialty certification program exists (e.g., the NCQA PCSP program), and should not be specifically validated by CMS. In addition, we are concerned that the existing recognition programs "teach to the test" rather than drive and support sustainable change. We support restricting the designation of PCMH status solely to primary care-focused patient medical homes and oppose awarding credit to specialty-focused medical homes.

Finally, we recognize that some TINs may have some practices with PCMH designation, and some without PCMH designation. Although, the AAFP recognizes that trying to separate out PCMH participants and non-participants would be overly burdensome. We believe it is unfair to small practices that have invested in PCMH recognition to be scored the same as practices that have not. Accordingly, we do not believe the full TIN should get CPIA credit simply because one site in the TIN has PCMH recognition. Granting PCMH CPIA credit to an entire TIN based on the PCMH recognition of one site within the TIN represents a huge opportunity for gaming of the system. A TIN should only receive PCMH CPIA credit in proportion to the number of practice sites within the TIN that have PCMH recognition.

3. CPIA Data Submission Criteria
a. Submission Mechanisms
CMS proposes that data be submitted via qualified registry, EHR, QCDR, CMS Web Interface, and attestation. An agreement between a MIPS-eligible clinician or group and a health IT vendor, QCDR, or quality registry for data submission for CPIA as well as other performance data submitted outside of CPIA could be contained in one agreement. An additional submission by a claims method would be used only to supplement CPIA submissions. For example, MIPS-eligible clinicians using telehealth with modifier GT could get automatic credit.

AAFP Response
The AAFP agrees that a clinician participating in telehealth and submitting claims for this service should receive automatic credit with no data submission required. We would also suggest that clinicians submitting these cognitive care codes [chronic care management (CCM), transitional care management (TCM), and advance care planning (ACP)] should get credit for CPIAs.

b. Weighted Scoring
CMS proposes to divide CPIA activities into medium- and high-weight categories. High-weight category activities are defined as:

- Being aligned with National-Quality Improvement Organization;
- The CPC;
- Programs that require performance of multiple activities such as the Transforming Clinical Practice Initiative (TCPI);

- Seeing new and follow-up Medicaid patients in a timely manner in the physician's state Medicaid programs;
- Activity identified as public health priority; and
- The PCMH.

CMS seeks comments on ways to simplify the CPIA score and factors they should take into consideration when trying to determine if an activity is weighted medium or high.

AAFP Response
Practices participating in transformation activities expend time, money, capital and human resources. Activities that require an additional investment in technology, like offering telehealth services, access to a patient portal, or participation in a QCDR should be categorized "high" instead of "medium." High-weighted activities could be considered those that require the addition of a staff person or the redistribution of an existing staff person's time to add capacity for care coordination and patient self-management support like health coaching. In addition, highly rated CPIAs should include activities that add functionality for co-located services like pharmacy and behavioral health.

With regards to continuing medical education (CME) and its ability to facilitate improved performance and/or patient outcomes in CPIAs—since 1947, the AAFP has contributed to the health of patients, families, and communities by helping our members improve their knowledge, professional competence, practice performance, and patient outcomes. We do so by setting and upholding the standards for lifelong learning and by providing CME activities that comply with those standards. In 2014, the AAFP Credit System awarded approximately 60,000 CME credits for activities designed to meet our eligibility requirements and improve patient care. CPIAs, as a part of MIPS, are transformational activities that practices can participate in to help achieve these goals. Aligning with CPIAs is performance improvement CME, which supports health care transformation by encouraging clinicians to reflect on current practice and engage them to make changes in their practice that ultimately improves the care that is delivered. There are now multiple examples in the literature that proves the value of performance improvement CME as a vehicle for not only promoting change, but also embedding that change into a practices' workflow so that observed improvement is sustained in the long term. Fundamentally, the objectives of CPIAs and performance improvement CME are congruent with the strategic goals of the Administration.

We believe that performance improvement CME activities that involve assessment and improvement of patient outcomes or care quality, as demonstrated by clinical data or patient experience of care data, including completion of an AAFP's "Performance Navigator" CME module should be included in the list of CPIAs as a high-weight activity. These activities may involve multiple interventions that are focused via an assessment of the current environment on individualized practice needs. They will also likely require redistribution of an existing staff person's time or a dedicated new staff person. Other high-rated activities should include establishment of a patient advisory council, risk-stratified care management, and shared decision-making (with the use of an evidence-based decision aid).

The AAFP supports CMS' intention to engage eligible clinicians in CPIAs. We recognize the complexity associated with designing a system that allows eligible clinicians the freedom to choose CPIAs that are relevant for their practice environments. However, we believe we can help CMS in this process. The AAFP has the infrastructure in place to accredit learning and performance improvement activities for health care professionals. Our accreditation systems

can track participation by eligible clinicians in activities that improve quality, practice performance, and patient outcomes. An additional data field could be added that would enable the providers of accredited educational activities to designate those activities that are MIPS-CPIA compliant. Then, the AAFP would report eligible clinician participation in such activities to CMS on a periodic basis. In addition to engaging CME accreditors to leverage existing oversight mechanisms and streamline eligible clinician's reporting requirements, this approach would also enable the nation's CME and non-physician continuing educational infrastructure to function as trusted intermediaries to engage the clinical community in CPIAs.

We strongly urge CMS to include in the final rule a role for CME accreditors (such as the AAFP) to facilitate the engagement, attestation, and auditing of eligible clinician's participation in CPIAs that is consistent with the aims of the Quality Payment Program (QPP). The AAFP is prepared to assist you, and we welcome any questions that you may have in this regard.

c. Submission Criteria
The agency proposes that high-rated CPIA would receive 20 points and medium-rated CPIA receive 10 points. To achieve the highest CPIA score, in most cases a MIPS-eligible clinician must get 60 points through a combination of medium and high activities. The exceptions to this are for small groups of 15 or fewer eligible clinicians; those practicing in rural and health professional shortage areas (HPSA); and non-patient facing eligible clinicians that only need to do two activities (either medium or high) to get the highest score or one CPIA for half the score. Those in an APM get 30 points for APM participation and need to select additional CPIAs for the additional 30 points. Eligible clinicians must select each QCDR CPIA separately and report separately on them to get credit for each. CMS seeks comment on expanding the CPIA inventory and what restrictions should be placed around CPIA measures and activities that incorporate QCDR participation.

AAFP Response
The AAFP agrees that those clinicians in small groups, rural settings, and HPSAs, will face challenges implementing the MIPS program, and we believe that eligible clinicians in medically underserved areas should be added to this list. Eligible clinicians in all of these categories face challenges related to lack of infrastructure and financial reserves that make undertaking and reporting CPIA difficult. Small group clinicians will be further handicapped since virtual groups are not an option in the first performance year. As noted above, CME that improves performance, however, will help this demographic of clinician meet their CPIA requirements.

Note, we do not think that non-patient facing clinicians fall into this same category. <u>The AAFP believes that non-patient facing clinicians should be able to choose enough CPIA to participate fully.</u>

When considering the QCDR, if activities are given the high weight as suggested above, an eligible clinician should be allowed to report on no more than one CPIA that involves a QCDR. If the score is retained at medium, the eligible clinician should be allowed to report on no more than two QCDR activities. The AAFP believes sub-specialties will primarily rely on QDCR to get full credit in this category without actively engaging in CPIA.

d. Required Period of Time for Performing an Activity
The agency proposes that each CPIA must be performed for at least 90 days during the performance year to get credit. In the future, this time period may be expanded or shortened and CMS seeks feedback in this regard.

AAFP Response
The AAFP supports a 90-day action period. We believe that less than 90 days would not be reasonable to make sustainable improvements.

4. Application of CPIA to Non-Patient Facing MIPS-Eligible Clinicians and Groups
CMS proposes non-patient facing MIPS-eligible clinicians and groups would receive 30 points for each CPIA regardless of the activity being medium or high. Several non-patient facing physician organizations suggested consideration for Appropriate Use Criteria (AUC) as a CPIA recognized under MIPS.

AAFP Response
The AAFP believes that non-patient facing clinicians should be able to choose enough CPIAs to obtain a full score of 60 with no modifications to the scoring system. We further agree that if they are already using AUC, they should be encouraged to choose another CPIA to report. Given that, and the fact that much of the AUC burden falls to primary care and not the clinician doing the reporting, CMS should limit non-patient facing clinicians to reporting no more than one AUC CPIA.

5. Special Consideration for Small, Rural, or HPSA Practices
As noted previously, the agency requires that consideration be given to small groups of 15 or fewer eligible clinicians, those practicing in rural and health professional shortage areas and non-patient facing eligible clinicians that only need to do two activities (either medium or high) to get the highest score or one CPIA for half the score.
CMS seeks comment on this proposal and on what activities would be appropriate for these practices for CPIA.

AAFP Response
The AAFP agrees that those clinicians in small groups, in rural settings, and HPSAs, will face challenges implementing the MIPS program. Note, we do not think that non-patient facing clinicians fall into this same category. We also suggest that clinicians in medically underserved areas be added to this exclusionary list. CPIAs for these specified practice types will be challenging. Specifically, these clinicians are handicapped since virtual groups are not an option in the first performance year. As noted previously, CME activities that involve assessment and improvement of patient outcomes or care quality, as demonstrated by clinical data or patient experience of care data, will help clinicians meet their CPIA requirements.

6. CPIA Subcategories
MACRA listed access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, and participation in APM as CPIA subcategories. CMS proposes to also include achieving health equity, integrating behavioral health and mental health, emergency preparedness and response. The agency seeks feedback on two categories for future inclusion, promoting health equity and continuity (e.g., treating Medicaid and dual eligible patients, maintaining adequate equipment for those with disabilities) and social and community involvement (e.g., measuring completed referrals, evidence of community and social services partnership). CMS also seeks feedback about what activities can demonstrate improvement over time.

AAFP Response
We think it is beyond the scope of this rule to propose new categories of CPIAs when we have not implemented the subcategories MACRA requires. Rather the proposed new subcategories could be incorporated into the CPIAs already in existence.

7. CPIA Inventory
The proposed rule suggests that guidelines for CPIA inclusion are based on one or more of the following criteria: relevance to a CPIA subcategory; achievement of improved beneficiary health outcomes; assistance for the practice in reducing health disparities; alignment with the PCMH; activities that MIPS-eligible clinicians or groups could perform; activities that are feasible to implement and that CMS can validate. CMS seeks comments on the inventory and suggestions for CPIAs in future years.

AAFP Response
We appreciate CMS giving practices engaged in TCPI credit for a CPIA. We encourage CMS to look for ways to use the proposed rule to encourage practices to enroll in TCPI by offering full credit for CPIA with no additional data needed to be gathered and submitted by practices.

8. CPIA Policies for Future Years of MIPS Program
For future years, CMS proposes that new CPIA subcategories must meet the following criteria: represent an area that could highlight improved beneficiary health outcomes; patient engagement and safety based on evidence; has a designated number of activities that meet criteria for a CPIA and cannot be classified under the existing subcategories; and new subcategories that would contribute to improvement in patient care practices or improvement in performance on quality measures and Resource Use performance category. CMS seeks feedback on these issues.

AAFP Response
We believe CMS should wait to learn from the CPIA categories that are implemented, and then decide what criteria are needed for new subcategories.

b. Request for Comments on Call for Measures and Activities Process for Adding New Activities and New Subcategories
The regulation discusses that in the future there will be a process for MIPS-eligible clinicians, groups, and other stakeholders to recommend activities for inclusion to CPIA inventory. In the future, CMS will award CPIA scores on performance and improvement. CMS seeks comments on this discussion and how to best collect such CPIA data and factor it into future scoring under MIPS.

AAFP Response
The CPIA performance category needs to learn from quality measure development. Quality measures now take approximately two years to be included in payer programs. CMS needs to prevent CPIA from becoming a similarly burdensome process. Anticipating that private payers will follow the lead of CMS and adopt CPIAs in their payment structure, the AAFP strongly believes that CMS should create a parsimonious and harmonized list of CPIAs which can be utilized by all payers and would prevent an overwhelming list in the future.

c. Request for Comments on Use of QCDRs for Identification and Tracking of Future Activities
In future years, CMS expects to learn more about CPIAs and how the inclusion of additional measures and activities captured by QCDRs could enhance the ability of MIPS-eligible

clinicians or groups to capture and report on more meaningful activities. CMS may propose use of QCDRs for identification and acceptance of additional measures and activities which encourages the use of QCDRs

AAFP Response
When considering the QCDR, if activities are given a high weight, an eligible clinician should be allowed to report on no more than one CPIA that involves a QCDR. If the score is retained at medium, the eligible clinician should be allowed to report on no more than two QCDR activities. The AAFP believes sub-specialties will primarily rely on QDCR to get full credit in this category without actively engaging in CPIAs.

g. ACI Performance Category
MACRA includes the meaningful use (MU) of certified EHR technology (CEHRT) as a performance category under the MIPS. It is referred to by CMS in this proposed rule as the ACI performance category. This category will be reported by MIPS-eligible clinicians as part of the overall MIPS program. The four performance categories shall be used in determining the MIPS CPS for each MIPS-eligible clinician. In general, MIPS-eligible clinicians will be evaluated under all four of the MIPS performance categories, including the ACI performance category.

AAFP Response
The AAFP was pleased that the MACRA in essence sunsets the EHR incentive program (Meaningful Use/MU) and harmonized the program with the value-based modifier and the Physician Quality Reporting System (PQRS). We believe that while MU resulted in greater adoption of health information technology, it has significantly missed the mark in improving care and the ability for eligible professionals to care for patients. Interoperability, which was the key tenant of the Health Information Technology for Economic and Clinical Health (HITECH) Act, is only marginally better than prior to the start of the MU program even after investing tens of billions of dollars. Also during the life of the MU program, we have seen a steady decline in EHR satisfaction and usability. We are also concerned that certified EHR technology still lacks the needed functionality and usability to drive toward the goals of improving the patient experience of care, improving the health of populations, and reducing the per-capita cost of health care. Although the proposed component of ACI improves on the requirements of the MU program, we believe the burden of compliance still outweighs the benefit that patients will experience.

At the time of passing the HITECH Act, there were no other significant levers to drive health care delivery reform. With the passage of the Affordable Care Act (ACA) and MACRA, this is no longer true. CMS now has the ability to implement policy focused on incentivizing outcomes instead of structural and process end points. We believe that the focus on structural and process measures, coupled with aggressive policy timelines, has led to many implementations detrimental to care efficacy and efficiency. Also, the variation in patient needs and medical practice makes it difficult to craft simple, one-size-fits-all policies. The result is a series of complex, fits-no-one policies that diverts practice resources away from care delivery to the management of administrative complexity and waste. With health IT adoption well underway and the utilization of health IT as the only way to achieve the desired outcomes efficiently and effectively, with value-based payment rewards, it is time to drop health IT utilization measures. Given this and the overall complexity of the MIPS program, which needs to be dramatically simplified to be successful, we believe the current proposal for ACI has missed the mark in a major way and demands reconsideration.

In reviewing the statues governing the MU program [American Recovery and Reinvestment Act (ARRA), ACA, MACRA], we believe there are only a few mandatory requirements for the ACI components:

- Eligible clinicians must use certified EHR technology (CEHRT).
- The requirements must include a prominent component of information exchange:
    - The measure of this must be at the "satisfaction of the Secretary."
    - CEHRT must be connected using standards to provide information exchange.
- Eligible clinicians must report quality measures and the reporting must be integrated across MU and PQRS.
- The Secretary shall seek to improve use of EHRs by requiring more stringent measures of MU over time.
- The EHR reporting period is defined as any period (or periods) as specified by the Secretary.
- In 2019 and beyond, the Secretary shall determine if a MIPS-eligible clinician is a meaningful user.
- MU must be a performance category for MIPS and be 25 percent of the composite score. That percentage can be reduced to no less than 15 percent at the discretion of the Secretary should MU adoption reach 75 percent.

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. First, we recommend that the certification process be improved to:

- Increase the testing requirements for interoperability, namely care transitions, secure messaging, and application programming interfaces (API);
- Increase the testing around the support of the common core clinical data set and its integration in the EHR technology; and
- Perform both benchmark and field testing of CEHRT to be sure these capabilities are available in the market place and can be deployed at the practice/hospital site.

Secondly, establish a post-market surveillance system to allow reporting by eligible clinicians for events where CEHRT is not living up to the certification requirements. Also allow reporting by patients and clinicians for events where MIPS-eligible clinicians did not have attested functionality available or there was information-blocking behavior. Reporting would help HHS track compliance with attestation and could be a stream of data to pinpoint needed audits.

Thirdly, we recommend that the requirements and scoring of ACI be replaced with the following:

- Base score requirement would still be 50 percent of the total score for ACI.
- To achieve a full-base score, the MIPS-eligible clinician must:
    - Use CEHRT and attest that it is in place for the reporting period;
    - An exclusion for periods of acceptable down time (system maintenance, switching of systems, decertification of current system, etc.) would be included as to not penalize eligible clinicians for situations outside of their control;
- Protect health information as currently proposed in this regulation;
- Performance score would still be 50 percent of the total score for ACI;
- MIPS-eligible clinicians would receive 5 points for each of the 10 measure specifications listed in the proposed rule if they attest that functionality was available for use during the reporting period (the same exclusion for acceptable down time would apply here).

While the AAFP disagrees that health IT utilization measures are useful in achieving the desired goals, we believe this AAFP proposal complies with current requirements in statue. It simplifies the ACI component without hindering progress toward the goals of the original MU program and the current MACRA proposal.

In addition to the new proposals for ACI, we believe that the government needs to ensure the last mile of the Direct exchange is completed for all those sending and receiving Direct messages and attachments. CMS, the Department of Veterans Affairs (VA), the Department of Defense (DoD), other federal agencies, and major health care payers need to ensure that eligible clinicians in the private sector have the capability to coordinate care easily utilizing the Direct exchange. To do this, we believe that the federal government should:

- Support the development of national provider directories that include provider Direct addresses;
- Ensure that certification of health IT addresses usability and ease-of-use of the Direct exchange, and the products are graded with respect to these qualities;
- Ensure that content or payloads delivered as attachments to Direct messages are made more uniform and capable of being computable by senders and receivers using the Direct exchange to share health information; and
- Financially penalize CEHRT vendors that participate in information blocking behavior and/or a determination is made that certified interoperability functionality is not functioning in the market as tested during certification.

h. APM Scoring Standard for MIPS-Eligible Clinicians Participating in MIPS APMs
CMS proposes that qualifying APM participants that are not MIPS-eligible could be excluded from MIPS and be considered Partial Qualifying APM Participants (Partial QP). Partial QPs are not MIPS-eligible unless they opt to report and be scored under MIPS. All other eligible clinicians participating in APMs are MIPS-eligible and subject to MIPS requirements.

For these Partial QPs, CMS aims to reduce the reporting burden so that eligible clinicians do not report to both APM and to MIPS. There will be specific criteria for the APMs that get preferred scoring under MIPS or "MIPS APMs." For the purposes of the APM scoring standard, CMS proposes to consider a participant in an APM Entity (an individual or a group). To be a "MIPS APM," a clinician or group must meet certain criteria:

1. APM entities participate in an APM under an agreement with CMS;
2. APM entities include one or more MIPS-eligible clinicians on a participation list;
3. The APM bases incentives on performance (at either the APM Entity or eligible clinician level) on cost/utilization or quality measures.

AAFP Response
The AAFP is very concerned about CMS's proposal to implement a "MIPS APM" category. In the design of this law and explanations provided by CMS staff in publicly-presented presentations before the proposed rule was released, the design was relatively simple and understandable. A National Provider Identifier (NPI) was in MIPS, reported to MIPS, and was rated and paid through MIPS. Alternatively, the NPI resided within an APM, met certain eligibility criteria and qualifications, and was paid through the metrics of that APM. There was little middle ground. The middle ground that did exist was that an NPI within an APM that fell below the low-volume threshold or did not meet all the eligibility criteria, those NPIs received their available

APM Shared Savings adjustment. Then, they received half credit on CPIAs and were to report to MIPS and receive a MIPS adjustment.

Unfortunately, throughout this section of the proposed rule, there are so many different rules and exceptions that no practicing physician could reasonably understand and report accurately to get a fair payment. For example, even the term "MIPS APMs," a hybrid of the two tracks otherwise designated in the law, is confusing to clinicians trying to grasp the already complicated nomenclature. We fear the proposed approach to "MIPS APMs" will penalize physician practices that were early adopters of the move to alternative payment models, such as first generation ACOs, and thereby undermine the intent of MACRA to move physicians to a payment model focused on quality and value.

To mitigate these negative consequences, we urge CMS to consider an approach that allows practices already participating in non-risk bearing APM entities to continue engaging in those models until other types of APMs become available, and until virtual group models are fully developed. Consistent with the spirit of MACRA, we urge CMS to exempt small practices from the MIPS APM provisions until other APM options, including virtual models, are available. Finally, absent any other changes to the proposed rule, we believe that scoring MIPS APMs in every category, with the same standards as other MIPS-eligible clinicians, protects program integrity and restores the intent of MACRA without the overly complex framework suggested in the rule.

6. MIPS CPS Methodology
(a) Performance Standards
The proposed rule discusses how MIPS-eligible clinicians will know the performance standard methodology for determining the measure and scoring methodology in advance of performance period, when possible.

AAFP Response
"When possible" cannot be used as a substitute for CMS being unready or not having installed the needed software and processes to publish information in advance.

(b) Unified Scoring System
CMS proposes that all Quality and Resource Use measures will be converted to a 10-point scoring system and that CMS generally would not include an "all-or-nothing" reporting requirement for MIPS. Clinicians who fail to report on an applicable measure or activity that is required, shall receive the lowest possible score for the measure or activity. CMS proposes to score only measures that meet certain standards to ensure reliability and validity and will encourage the focus on high priority areas. Performance at any level would receive points towards the performance category scores.

AAFP Response
The AAFP supports allowing clinicians to receive credit for all their efforts. We particularly support elimination of the all-or-nothing approach in the QPP. However, we must point out that the current ACI proposed base score requirements do not support elimination of all-or-nothing, since a score of zero will be assigned unless clinicians implement every component of the ACI category. Therefore, in accordance with CMS's stated intentions to drop the all-or-nothing measurement approach, we urge more flexibility in this category. Our new proposed construct for ACI eliminates this all-or-nothing method.

(c) Baseline Period
CMS proposes to establish the baseline period as two years prior to the performance period and suggests this period would be used to set benchmarks for the Quality category (except for new measures), which the baseline would be the current performance period. For the Resource Use category, the performance period will be used to set benchmarks. An alternate proposal would use the baseline period to set benchmarks for the Resource Use category and assess performance at measure level.

AAFP Response
The AAFP cautions that there may be misalignment when using benchmarks from one year for Resource Use and a different year for quality measures. While quality is always a top priority, quality focus is driven also by payment incentives. The AAFP strongly encourages CMS to improve their processes, software, and technology—just as physicians have been required to do—to allow more real-time analysis and feedback. A two-year delay in providing physicians with this data seriously undercuts the value and utility of quality improvement of data. Ideally, all categories should use the same year to determine benchmarks.

(2) Scoring the Quality Performance Category
(a) Quality Measure Benchmarks
CMS proposes to break baseline period measure performance into deciles and to create separate benchmarks for submission mechanisms that do not have comparable measure specifications. Further, the agency proposes to develop separate benchmarks for EHR submission options, claims submission options, QCDRs, and qualified registries submission options. Regarding the Web Interface option, CMS proposes to use the benchmarks from the Medicare Shared Savings Program and apply the MIPS method of assigning 1-10 points to each measure. All scores below the 30th percentile would be assigned a value of 2.

CMS also proposes to weight the performance rate of each MIPS-eligible clinician and group submitting data on the quality measure by the number of beneficiaries used to calculate the performance rate. CMS would include APM Entity submissions in the benchmark without scoring APM entities using this methodology. CMS proposes that at least 20 MIPS-eligible clinicians must report the measure and meet the case minimum for the benchmark calculation. CMS would exclude measures with a 0% performance rate.

AAFP Response
Establishing dissimilar benchmarks for the same measures for different reporting mechanisms seems contrary to the definition and purpose of a benchmark. The AAFP urges CMS to eliminate unnecessary and counterproductive complexity from this program. We support using the same benchmarks across reporting mechanisms for the same measure. We realize documentation may affect the performance on electronic measures. However, such documentation issues need to be addressed and corrected by clinicians prior to the reporting period for measures they plan to report using electronic mechanisms. We support that CMS monitor the need for separate benchmarks for measures that contain only data for Medicare patients to determine if separate benchmarks should be established (e.g., claims and Web Interface).

The AAFP agrees that 0% performance rates should be excluded from benchmark calculations. Furthermore, we agree with weighting the performance rates according to the number of beneficiaries.

The AAFP agrees the performance period should be used to determine a benchmark for new measures. We support using a consistent baseline period for all measures and moving the baseline, reporting, and performance periods as closely together as possible.

The AAFP agrees additional credit should be given for reporting new measures to allow for building infrastructure and learning the intricacies of the measure specifications. We support assigning a 3 as the lowest score for new measures.

The AAFP has serious concerns that, without timely and transparent communication relative to benchmarking, clinicians cannot make appropriate choices about technology and practice improvement investments in time for the start of the 2017 performance period.

(b) Assigning Points Based on Achievement
CMS proposes to establish benchmarks using a percentile distribution, separated by decile categories. For each set of benchmarks, CMS proposes to calculate the decile breaks for measure performance and assign points for a measure based on the decile range in which the performance rate falls. Eligible clinicians would receive at least 1 point for reporting a measure if they meet the case minimum. Topped out measures would be scored and weighted differently. Rather than assigning up to 10 points per measure, CMS proposes to limit the maximum number of points a topped out measure can achieve based on how clustered the scores are. All scores within the cluster would receive the same score.

AAFP Response
We support the use of the decile scoring method, as opposed to a flat percentage, for non-topped-out measures. We support limiting the maximum score of topped-out measures by scoring all scores within a cluster the same. The AAFP supports limiting the ability to report no more than two topped-out measures to avoid potential “gaming”. The AAFP encourages CMS to actively identify topped-out measures and promptly remove them well in advance (i.e., one year) of the reporting year in order to allow physicians to adjust their quality reporting plans and workflow.

(c) Case Minimum Requirements and Measure Reliability and Validity
CMS proposes a 20-case minimum, except for the all-cause hospitalizations measure of 200, which CMS proposes does not include MIPS-eligible clinicians who individually report or solo practitioners or groups of two-to-nine MIPS-eligible clinicians. CMS would exclude measures if they are found to be unreliable, with excluded measures having no impact on the score.

AAFP Response
The AAFP recognizes the current use of measures, such as the all-cause readmission measure in VM. However, in our experience, physicians’ interaction with and understanding of the VM program and the resultant QRURs are low. The EIDM registration is cumbersome and time-consuming to complete (often taking several weeks to receive approval); the required roles are not obvious; the current portal is not intuitive to navigate; reports take significant time to download; and once downloaded, are difficult and time-consuming to interpret. We propose a phased-in approach for population-based and global outcome measures in which the MIPS program would begin with the six measures (including one cross-cutting and one outcome-based measure) for scoring. We believe that population-based measures should be tested in the program before composite performance scores are based on their results. For the first two years, CMS needs to collect and disseminate data to eligible clinicians on global outcome and

population-based measures so they can learn about measurement at a population level and CMS can learn how population-level measurement will impact the MIPS program.

(d) Scoring for MIPS-Eligible Clinicians that Do Not Meet Quality Performance Category Criteria
CMS asks for feedback on safeguards that should be implemented to ensure that physicians submit measures that meet the required case minimum. The agency also requests input on validation processes to follow if a clinician is unable to report on quality measures as required.

AAFP Response
MIPS clinicians should be required to report only measures that fulfill the minimum sample size requirement of 20 patients. If sufficient measures or patients cannot be reported using specialty-specific measures, then cross-cutting measures must be used to complete the set of six measures with a sample size of 20 patients. This approach will encourage the development of a sufficient number of appropriate measures by all specialties to bring parity to quality reporting requirements.

The past Measure Applicability Validation (MAV) process (which was applied when a clinician reported fewer than the required measures) was difficult to understand and implement. The AAFP believes confusion can be avoided in MIPS by enforcing equitable requirements for all clinicians, with no exceptions. Clinicians that do not report at least six measures—including a cross-cutting and outcome-based measure with a sample size of at least 20 patients—should receive a score of zero for each measure not meeting the requirement.

6.a (2)(e) Incentives to Report High Priority Measures
CMS proposes 2 bonus points for each outcome and patient experience measure, as well as 1 bonus point for other high-priority measures over and above those required. Neither population-based measures, nor a performance rate of zero would earn bonus points. The agency also proposes that bonus points be available for measures that are not scored (not included in the top six measures for the quality performance category score) as long as the measure has the required case minimum and data completeness.

AAFP Response
We appreciate the effort aimed at establishing a bonus structure for activities that encourage reporting high-priority measures. However, the proposed structure is too complex and will be misunderstood by most clinicians, particularly those in smaller practices that lack extended analytic support. Lack of understanding of how to earn bonus points will place smaller practices at a disadvantage compared to larger practices. As people become more accustomed to MIPS, the bonus point structure may be more useful. Therefore, the AAFP recommends the bonus point structure be delayed until future years.

(f) Incentives to Use CEHRT to Support Quality Performance Category Submissions
In addition to its high-priority bonus, CMS proposes 1 bonus point under the quality performance category score, and up to a maximum of 5% of the denominator of the quality performance score, if the eligible clinician performs “end-to-end electronic reporting” (i.e., use of EHR to document demographic and clinical data elements; export and transmit data electronically to a third party or directly; or to aggregate, calculate, filter, and submit electronically with a third party). This incentive is available for all submission methods except claims.

AAFP Response
We support efforts aimed at establishing a bonus structure for electronic reporting. However, reporting through a Qualified Registry and through the Web Interface may or may not involve end-to-end electronic reporting since manual abstraction of data is frequently used to supplement both mechanisms. It is not clear how CMS will determine which measures qualify for end-to-end electronic reporting. Will the vendor make this determination? Will the provider attest to such? The AAFP believes it will be difficult or impossible to make such a determination. While we recommend delaying the bonus structure until future years, if the bonus structure is maintained, we recommend eliminating the "end-to-end" language and awarding bonus points for every submission mechanism except claims. While the opportunity to earn bonus points is appealing, the current proposal for bonus points is not meaningful or helpful, and demonstrates the unnecessary complexity and burden within the proposed rule. Currently, bonus points are tied to adoption and integration of technology into a practice, with additionally complex and burdensome requirements. Successfully navigating the challenges required to earn a bonus point would result in the bonus point becoming a fraction of a fraction of points, which then becomes a percentage within the overall score. The potential bonus point becomes so diluted it does little to motivate eligible clinicians to invest the energy or resources required to earn the fraction of the fraction of a percentage attributed to the bonus point. Therefore, it just adds complexity and the AAFP does not support the bonus points at this time.

As expressed earlier, the AAFP believes the proposed bonus structure is too complex, will be misunderstood by most clinicians, especially those without dedicated analytic support, and should be delayed until future years.

(g) Calculating the Quality Performance Category Score
(i) Calculating the Quality Performance Category Score for non-APM Entity, non-CMS Web
(ii) Calculating the Quality Performance Category for CMS Web Interface Reporters

To calculate the Quality performance category score for all mechanisms, except the Web Interface, CMS proposes to sum the weighted points assigned for the measures required by the Quality performance category criteria, plus the bonus points and divide by the weighted sum of total possible points. If the practice elects to report more measures than required, CMS would use only measures with the highest score, plus required measures. Regarding Web Interface reporters, CMS proposes to score all measures, and this mechanism would always earn bonus points for high-priority measures, as long as all measures are reported.

AAFP Response
We support calculating the Quality performance category score by summing the weighted points assigned for measures and dividing by the weighted sum of total possible points. As expressed earlier, the AAFP believes the proposed bonus structure is too complex, will be misunderstood by most clinicians, especially those without dedicated analytic support, and should be delayed until future years.

(h) Measuring Improvement
CMS discusses that improvement shall be calculated for the Quality and Resource Use categories beginning with year two and may be calculated for CPIA and ACI. If clinicians report the same measures, then the regulation proposes three methodologies for incorporating improvement into the Quality score, the Hospital Value-Based Purchasing (HVBP) (Option 1) method, MSSP method, and Medicare Advantage 5-star rating.

AAFP Response
We favor the simplicity of the HVBP approach for calculating measure improvement. However, this approach presents challenges when the clinician changes measures from year to year or changes between group and individual reporting. We anticipate this will take place frequently given the large number of measures available for reporting. If physicians choose to report different measures each year, or change between reporting as a group or individual, then the opportunity to earn improvement points would not be available and the Quality score would be determined solely by the achievement score. However, improvement points should not be compromised if measures are removed from one year to the next. We oppose the MSSP method due to its reliance on bonus points, which we believe are too complex to implement at this time. We oppose the Medicare Advantage 5-star rating method due to its complexity and for the likelihood of it being misunderstood by clinicians.

(3) Scoring the Resource Use Performance Category
(a) Resource Use Measure Benchmarks
CMS seeks comment on establishing benchmarks for the Resource Use category based on the performance period, instead of using a baseline.

AAFP Response
We support using the same baseline for all categories and moving the baseline closer to the performance period.

(b) Assigning Points Based on Achievement
CMS seeks comment on using deciles or an alternative methodology.

AAFP Response
We support using the decile approach for both the Quality and Resource Use categories. The same methodology should be used across categories to reduce complexity.

(c) Case Minimum Requirements
CMS proposes to establish a 20-case minimum for each resource use measure and notes that this would include the Medicare Spending per Beneficiary (MSPB) measure.

AAFP Response
The AAFP opposes use of the total per capita cost and MSPB since the measures were developed for hospital comparison. These two measures are not appropriate for physicians outside an Advanced APM because they assign responsibility for costs to physicians that have no control over such costs. At this time, the most appropriate measures for Resource Use comparisons will be the clinical condition and treatment episode-based measures. Factors such as patient choice of treatment options; patient self-referral to specialists; specialist determination of the best course of care; and lack of incentives and mechanisms to control costs if the physician is not part of an Advanced APM, place total per capita costs and MSPB measures outside the control of primary care physicians. The AAFP opposes total per capita and MSPB measures and urges CMS to use a reliability of 0.7 for any calculation of case minimums within the Resource Use category.

We recognize that if CMS agrees to eliminate total per capita cost and MSPB measures, some eligible clinicians may not have any relevant Resource Use measures, because the available clinical condition and treatment episode measures do not apply to them. In that circumstance,

we believe that CMS should reallocate the Resource Use weight to the other three CPS elements (i.e. quality, CPIA, and ACI).

(d) Calculating the Resource Use Performance Category Score
CMS seeks comment on the proposal to average all the scores of all the Resource Use measures attributed to the MIPS-eligible clinician. All measures in the Resource Use performance category would be weighted equally and no bonus points would be available.

AAFP Response
We agree with the proposed methodology and encourage frequent, timely feedback reports moving toward real-time feedback.

(4) Scoring the CPIA Performance Category
(a) Assigning Points to Reported CPIAs
CMS discusses whether to assign points for each reported activity as high (20 points) or medium (10 points). The agency would rate activities as high, based on the extent to which they support the PCMH model, as well as with CMS priorities for transforming clinical practice. Additionally, activities that require performance of multiple actions, such as participation in the TCPI, participation in a MIPS-eligible clinician's state Medicaid program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) are weighted as high.

AAFP Response
Practices participating in transformation activities expend capital and human resources. Activities that require an additional investment in technology, such as offering telehealth services, access to a patient portal, or participation in a QCDR, should be categorized as high. High-weighted activities could be considered those that require the addition of a staff person or the redistribution of an existing staff person's time to add capacity for care coordination and patient self-management support. In addition, high-rated CPIAs should include activities that add functionality for co-located services, such as pharmacy and behavioral health. CME activities that involve assessment and improvement of patient outcomes or care quality, as demonstrated by clinical data or patient experience of care data, including completion of the AAFP's Performance Navigator CME program, should be included in the list of CPIA activities as a high-weight activity. Other high-rated activities should include establishment of a patient advisory council, risk-stratified care management, and shared decision-making (with the use of an evidence-based decision aid).

(b) CPIA Performance Category Highest Potential Score
The regulation discusses there is variability in the level that each MIPS-eligible clinician would perform a CPIA, but the agency currently does not have a standard way of measuring that variability. In future years, CMS plans to capture data and develop a baseline for measuring CPIA improvement. The regulation further discusses the belief that a top-performing small practice (consisting of 15 or fewer professionals), practice in a rural or HPSA, or a non-patient facing MIPS-eligible clinician would be asked to report on at least two activities.

AAFP Response
Non-patient facing clinicians should not get special consideration (as discussed previously under the Resource Use section). We believe there are ample activities under CPIA for participation of all physicians, and practice improvement is equally important for all, including non-patient facing. We agree that small, rural, HPSA practices warrant special consideration

under CPIA and urge CMS to add medically underserved areas to this group. Variability should not be a concern in the CPIA category, as we believe variability will present itself in the performance rates of the Quality and Resource Use categories.

(c) Points for Certified-PCMH or Comparable Specialty Practice
MACRA specifies that a MIPS-eligible clinician who is in a practice that is certified as a PCMH or comparable specialty practice must be given the highest potential score for the CPIA performance category for the performance period. CMS proposes that PCMH practices are those that have received accreditation from the Accreditation Association for Ambulatory Health Care, the National Committee for Quality Assurance (NCQA), The Joint Commission, and the Utilization Review Accreditation Commission (URAC); or are a Medicaid Medical Home Model or Medical Home Model. CMS further discusses that those who participate in a CMS study on CPIA and measurement would receive the maximum possible number of points.

AAFP Response
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 supports the medical home and intends for it to be a model recognized as an Advanced APM. The delivery of high-performing team-based patient-centered primary care is at the heart of the medical home model of care. A significant body of evidence clearly shows the medical home driving reductions in health care costs and/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 model. 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.

The AAFP supports the inclusion of the four nationally recognized medical home programs outlined in the regulation; however, we strongly recommend expansion beyond these four organizations. The AAFP believes strongly 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 PCMH. In addition, 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 their definition of PCMH to specifically be inclusive of programs that have a demonstrated track record of support by non-Medicare payers, state Medicaid programs, employers, and/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 Patient-Centered Medical Home and the five key functions of the CPC initiative.

The AAFP recommend 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 developed and adopted in February 2007. CMS could use these guidelines in exercising such a deeming authority. In addition, the AAFP encourages the inclusion of state-based, payer sponsored, or regional PCMH recognition programs.

The AAFP urges CMS to consider the inclusion of state-based, payer-sponsored, or regional PCMH recognition programs. These programs often provide more direct support and lower expenses for practices, while being customized to the need of health care consumers in that region.

Regarding the specialty designation of medical homes, while the standards for specialist medical home certification under the 2016 NCQA PCSP program align much more closely with the PCMH standards than in the past and while these standards call for expanded coordination and collaboration with primary care, we believe a specialty medical home designation alone, in the absence of a primary care PCMH, is not sufficient to warrant special treatment under MIPS. Specialty practices support and complement a primary care PCMH, but do not replicate all aspects of PCMH and do not replace the need for a primary care medical home. We also are concerned that only one such specialty certification program exists—the NCQA PCSP program—and should not be specifically validated by CMS. In addition, we are concerned that the existing recognition programs "teach to the test" rather than drive and support sustainable change. We support restricting the PCMH designation solely to primary care-focused patient medical homes and oppose awarding credit to specialty-focused medical homes.

(d) Calculating the CPIA Performance Category Score
To determine the CPIA performance category score, CMS proposes to sum the points for all of the MIPS-eligible clinician's reported activities and divide by the proposed CPIA maximum score of 60. CMS will consider modifications in future years.

AAFP Response
The AAFP supports scoring the CPIA category as described. However, the AAFP believes non-facing clinicians must be held accountable for practice improvement similar to their patient-facing peers. Non-patient facing clinicians should be able to choose enough CPIA activities to score 60 points and do not warrant special consideration. The AAFP believes those clinicians in small groups, HPSAs and rural areas deserve special consideration and supports adding medically underserved areas to this group for special consideration.

Clinicians should be allowed to report the same activities in the first two years of MIPS, but this may need to be revisited in the future as more experience is gained in the CPIA category.

(5) Scoring the ACI Performance Category
CMS further discusses moving away from the "all-or-nothing" scoring approach used in the Medicare EHR Incentive Program. CMS then proposes a methodology to score ACI based on both participation (base score) and performance. CMS proposes awarding bonus points under the Public Health and Clinical Data Reporting objective.

AAFP Response
As stated earlier, we believe the requirements of the base score under ACI are reflective of a blatantly "all-or-nothing" strategy, and we encourage CMS to revisit these requirements. Our ACI replacement proposal eliminates the all-or-nothing nature of CMS's proposed base score. In addition, we are generally opposed to the proposed bonus point structure, as we believe it is too complex for clinicians in practices who lack dedicated analytic support. We recommend elimination of the bonus structure until further experience is gained to reduce complexity.

b. Calculating the CPS
CMS proposes to calculate the CPS using a scale of 0-100 for each MIPS-eligible clinician for a specific performance period. The CPS is the sum of the products of each performance category score and each performance category's assigned weight multiplied by 100.

AAFP Response
We appreciate the simplicity of this CPS explanation and support the calculation.

(1) Formula to Calculate the CPS
(a) Accounting for risk factors
The regulation discusses how ASPE is conducting studies on risk adjustment for socioeconomic status and the impact on quality measures, and how CMS may incorporate this information in future rulemaking.

AAFP Response
We appreciate that socioeconomic status requires further study and may be incorporated into future risk adjustments. CMS is obligated to come up with a solution that prevents Medicare, Medicaid, dual-eligible beneficiaries, and other disadvantaged groups from losing access due to a negative impact on quality measures. However, clinicians currently serving these populations should not be penalized under MIPS because CMS has not yet developed a solution.

The risk-stratification methodology must be as transparent and credible, as well as simple as possible.

The AAFP also supports reducing health disparities as a part of care delivery and urges CMS to move forward with expanding its risk-adjustment methodology in quality measures to incorporate social and economic factors such as race, income, education, and region. Risk adjusting for socioeconomic status ensures the measures are fair and sets the standard for comparison of physician performance by adjusting for factors outside of the physician's control. Failing to adjust could lead to inaccurate conclusions concerning physician performance. As a result, further disparities in care could be magnified.

(2) CPS Performance Category Weighting
CMS proposes to assign a weight of zero to categories for which there are insufficient measures available and redistribute the weights to other categories. With regard to the Quality and Resource Use categories, CMS would not calculate a performance score if there are no

measures that meet case minimums or are without a benchmark. For the Quality category, CMS anticipates clinicians will select the measures most relevant to their practice, and in most circumstances, have a sufficient number of cases. CMS will monitor trends in reporting to identify gaming. In the Resource Use category, if too few cases are attributed, CMS will not score the category. In terms of CPIA, CMS believes all physicians should have sufficient activities and will receive a score. For the ACI category, CMS recognizes that some specialties may not have sufficient measures.

CMS proposes that CPIA is the only category that will always have a performance score. The agency proposes that if a MIPS-eligible clinician receives a score for only one performance category, the agency would assign an adjustment factor of 0% for the year.

AAFP Response
Reweighting due to insufficient quality measures will not be an issue if all clinicians are required to meet the same quality measure reporting requirements. Consistency in requirements will reduce complexity and eliminate inequities in the QPP. Primary care physicians have demonstrated a commitment to improvement and have designed an abundance of quality measures. That same commitment should be expected of all specialties, as each has had many years to develop sufficient quality measures. If acceptable specialty-based quality measures are unavailable, clinicians should be required to report cross-cutting measures or receive a zero for either unreported measures or measures without a sufficient number of patients. CMS's continued willingness to make allowances for this lack of specialty-based measures places specialties at an advantage over primary care providers, both in terms of performance under QPP and in terms of resources expended to support quality improvement.

We agree that reweighting the Quality score would be appropriate if a clinician does not receive a Resource Use or ACI score.

We agree, in concept, with the proposal that if a MIPS clinician receives a score for only one performance category, an adjustment factor of 0% should be assigned for the year. However, if all clinicians are held to the same requirement—reporting six quality measures, including one outcomes-based measure and one cross-cutting measure with a sufficient number of patients—then all clinicians should have a score in at least two categories (CPIA and Quality). Thus, there would be no need to assign an adjustment factor of 0%.

7. MIPS Payment Adjustments
a. Payment Adjustment Identifier and CPS Used in Payment Adjustment Calculation and
CMS proposes to use a single identifier—TIN/NPI—for all MIPS-eligible clinicians, regardless of whether the TIN/NPI was measured as an individual, group, or APM Entity group. In other words, a TIN/NPI may receive a CPS based on individual, group, or APM Entity group performance, but the payment adjustment would be applied at the TIN/NPI level. CMS is proposing to use the single identifier for the payment adjustment for the following reasons:

- Using TIN/NPI would allow CMS to correctly identify which TIN/NPIs are still MIPS-eligible clinicians after exclusion criteria are applied.
- TIN/NPI is mutually exclusive on all of the agency's measurement identifier options. Therefore, CMS believes this identifier can be used consistently for individual, group, or APM scoring standard identifiers, all of which are not mutually exclusive.

AAFP Response
The AAFP supports the agency's proposal. In addition to the reasons noted by CMS, the AAFP notes that section 1848(q)(6) of the Act (MIPS Payments), as added by MACRA, consistently refers to application of the adjustment factor at the level of the MIPS-eligible clinician. As already noted, the AAFP supports identifying MIPS-eligible clinicians by a combination of TIN and NPI.

ii. CPS Used in Payment Adjustment Calculation
In general, CMS proposes to use the CPS associated with the TIN/NPI combination in the performance period. For groups submitting data using the TIN identifier, CMS proposes to apply the group CPS to all the TIN/NPI combinations that bill under that TIN during the performance period. For individual MIPS-eligible clinicians submitting data using TIN/NPI, CMS proposes to use the CPS associated with the TIN/NPI that is used during the performance period. For eligible clinicians in MIPS APMs, CMS proposes to assign the APM Entity group's CPS to all the APM Entity Participant Identifiers that are associated with the APM Entity on December 31 of the performance period. For eligible clinicians that participate in APMs for which the APM scoring standard does not apply, CMS proposes to assign a CPS using either the individual or group data submission assignments.

In cases where there is no CPS associated with a TIN/NPI from the performance period, CMS proposes to use the NPI's performance for the TIN(s) under which the NPI was billed during the performance period. If the MIPS-eligible clinician has only one CPS associated with the NPI from the performance period, then CMS proposes to use that CPS.

In scenarios where the MIPS-eligible clinician billed under more than one TIN during the performance period, and the MIPS-eligible clinician starts working in a new practice or otherwise establishes a new TIN that did not exist during the performance period, CMS proposes to use a weighted average CPS based on total allowed charges associated with the NPI from the performance period. CMS also proposes an alternative proposal where, in lieu of taking the weighted average, CMS captures the highest CPS from the performance period. CMS believes the alternative approach rewards eligible clinicians for their prior performance and may be easier to implement in year one of MIPS. The agency's concern with this alternative approach is that the highest CPS may represent a relatively small portion of the eligible clinician's practice during the performance period.

CMS also considered, but is not proposing, a policy allowing performance to follow the group (TIN) rather than the individual (NPI). In other words, the MIPS-eligible clinician's performance would be based on the historical performance of the new TIN, to which the MIPS-eligible clinician moved after the performance period, even though this MIPS-eligible clinician was not part of the group during the performance period. This is consistent with the VM policy and would create incentives for MIPS-eligible clinicians to move to higher-performing practices. It would also provide a lower burden for practice administrators, as all MIPS-eligible clinicians in the TIN would have the same payment adjustment. On the other hand, having performance follow the TIN creates some challenges. For instance, MIPS-eligible clinicians who earn a positive adjustment based on their performance during the period would not retain the positive adjustment if the new TIN has a lower CPS, thus having performance following the TIN could create some unanticipated issues with budget neutrality if high-performing TINs expand.

In some cases, a TIN/NPI could have more than one CPS associated with it from the performance period (e.g., a MIPS-eligible clinician has a CPS for an APM Entity and a CPS for

a group TIN). If a MIPS-eligible clinician has multiple CPSs, CMS proposes a multi-pronged approach to select the CPS that would be used to determine the MIPS payment adjustment. First, CMS proposes that if a MIPS-eligible clinician participates in a MIPS APM, then the APM Entity CPS will be used instead of any other CPS (such as a group TIN CPS or individual CPS). CMS proposes that if a MIPS-eligible clinician has more than one APM Entity CPS for the same TIN (by participating in multiple MIPS APMs), CMS would apply the highest APM Entity CPS to the eligible clinician. Second, if a MIPS-eligible clinician reports as a group and as an individual, CMS would calculate a CPS for both the group and individual identifier, using the highest CPS for the TIN/NPI.

AAFP Response
In general, the AAFP supports the proposal to use the CPS associated with the TIN/NPI combination in the performance period. The AAFP also supports the proposal to use the NPI's performance for the TIN(s) under which the NPI was billed during the performance period in cases where there is no CPS associated with a TIN/NPI during that span.

The AAFP's support extends to the proposal to use a weighted average CPS based on total allowed charges associated with the NPI from the performance period in scenarios where the MIPS-eligible clinician billed under more than one TIN during the performance period, and the MIPS-eligible clinician starts working in a new practice or otherwise establishes a new TIN that did not exist during the performance period. We think this proposal makes more sense than the agency's alternative proposal to take the highest CPS from the performance period. As CMS notes, the alternative approach may reward eligible clinicians for prior performance that represent a relatively small portion of the eligible clinician's practice during the performance period.

The AAFP supports the agency's inclination not to have the performance follow the group (TIN) rather than the individual (NPI). We acknowledge that such an approach would be administratively simpler for group practice administrators. However, as CMS observes, it would penalize eligible clinicians who earned a positive adjustment based on their performance during the performance period if their new TIN had a lower CPS. It would also create an incentive for poor performers to move to high performing groups solely for the purposes of avoiding a negative payment adjustment. We believe MIPS-eligible clinicians should be accountable for their performance when it is accurately and appropriately measured. Having performance follow a group rather than an individual is contrary to that principle.

Finally, in cases where a TIN/NPI could have more than one CPS associated with it from the performance period, we generally support the proposed multi-pronged approach to select the CPS that would be used to determine the MIPS payment adjustment. As we understand it, that approach gives priority to the CPS of an APM Entity. We believe this is consistent with encouraging eligible clinicians to be part of APM entities.

The AAFP disagrees with the proposals in which CMS attempts to:

- Apply the highest APM Entity CPS to the eligible clinician in cases where a MIPS-eligible clinician has more than one APM Entity CPS for the same TIN (by participating in multiple MIPS APMs); and
- Calculate a CPS for both the group and individual identifier and use the higher CPS for the TIN/NPI in cases where a MIPS-eligible clinician reports as both a group and as an individual.

Instead, the AAFP recommends that in these scenarios CMS use a weighted average CPS based on total allowed charges associated with the NPI from the performance period, just as it proposes to do when a MIPS-eligible clinician bills under more than one TIN during the performance period and starts working in a new practice or otherwise establishes a new TIN that did not exist during the performance period. Simply using the highest CPS may reward eligible clinicians for prior performance representing a relatively small portion of his or her practice during the period in question. A weighted average approach takes into account the eligible clinician's entire performance during the period and holds the individual accountable for that entire performance.

b. MIPS Adjustment Factors
a. Determining the Performance Thresholds
(1) Establishing the Performance Threshold
CMS proposes (at §414.1305) to define the term "performance threshold" as the level of performance established for a performance period at the CPS level. To establish the performance threshold for the 2019 MIPS payment year, CMS proposes to model 2014 and 2015 Part B allowed charges, 2014 and 2015 PQRS data submissions, 2014 and 2015 QRUR and supplemental QRUR feedback data, and 2014 and 2015 Medicare and Medicaid EHR Incentive Program data. For the 2019 MIPS payment year, CMS proposes to set the performance threshold at a level where approximately half of the eligible clinicians will be below and half will be above that marker. CMS believes this is consistent with the intent of section 1848(q)(6)(D)(i) of the Act, which requires the performance threshold in year three and beyond to be equal to the mean or median of CPS from a prior period. CMS will determine the performance threshold in accordance with the methodology established in the final rule and publish the threshold on the CMS website prior to the performance period.

AAFP Response
With respect to establishing the performance threshold for 2019, the AAFP repeats our response to the RFI CMS issued last fall.

First, if CMS wants to use existing data on Quality and Resource Use measures as a baseline, threshold, or benchmark, that data must align with the measures included in MIPS in 2019. Where it does, CMS can use the data to calculate composite scores in much the same way it will do so under MIPS and use the mean or median of those composite scores to create performance thresholds for the first two years of the program. Where the data does not align exactly, CMS should not use it for this purpose.

While MACRA states a prior year will set the performance baseline for a practice, the AAFP strongly encourages CMS to consider the issues of having performance data from a different program used as the baseline performance data for the MIPS. For a physician to understand how his or her performance is being measured and what score is expected, the benchmarks for both quality and resource use measures need to be published in advance of the performance year. Additionally, the AAFP urges CMS to hold the benchmark steady for at least two years, if not longer—as is done in the ACO MSSP—instead of reassessing after each performance year. Frequent updating of these benchmarks undermines the business case for providers to improve the effectiveness of care delivery through investments..

The AAFP believes there should be a fairness of thresholds that address the differences in panel composition, available resources, etc., among small and large practices. A one-size-fits-

all approach will not lead to equally distributed success among providers. We would ask that CMS consider stratification of benchmarking when scoring providers. Comparing group practices to similar group practices and solo practitioners to similar solo practitioners could provide more accurate data related to a provider's efforts to improve patient care.

To the extent that CMS is using 2014 and 2015 PQRS data submissions in setting the initial performance threshold for the MIPS payment adjustment, we recommend CMS exclude data submitted via the Measures Groups reporting, which requires only a non-random sample of 20 patients per measure, and clinicians are able to cherry-pick their sample to achieve high performance rates. Such high rates are not representative of actual rates for the entire population and should not be used when establishing performance thresholds.

We agree with CMS that, for the 2019 MIPS payment year, the performance threshold should be set at a level where approximately half of the eligible clinicians would be below the performance threshold and half would be above it. As noted in the proposed rule, this is consistent with the intent of section 1848(q)(6)(D)(i) of the Act, which requires the performance threshold in year three and beyond to be equal to the mean or median of CPS from a prior period. The agency's proposal sounds as if it intends to use the median—a better measure of central tendency than the mean, which can be skewed by outlier values.

(2) Additional Performance Threshold for Exceptional Performance
CMS proposes (at §414.1305) to define the additional performance threshold as an additional level of performance, in addition to the aforementioned threshold, for a performance period at the CPS level at or above that which a MIPS-eligible clinician may receive an additional positive MIPS adjustment factor. CMS proposes (at §414.1405(e)) the following methods for computing the additional performance threshold: the threshold shall be equal to the 25th percentile of the range of possible CPS above the performance threshold; or it shall be equal to the 25th percentile of the actual CPS for MIPS-eligible clinicians with CPS at or above the performance threshold with respect to the prior period used to determine the performance threshold.

Since CMS will not have any actual CPS for MIPS-eligible clinicians to use for purposes of defining an additional performance threshold under the methodology proposed above for 2019, CMS proposes to establish the additional performance threshold at the 25th percentile of the range of possible CPS above the performance threshold. CMS intends to publish the exceptional performance threshold with the performance threshold prior to the performance period.

AAFP Response
The proposed definitions are consistent with the statute. We agree with the proposal to establish the additional performance threshold for 2019 at the 25th percentile of the range of possible CPS above the performance threshold, given that CMS will not have any actual CPS for MIPS-eligible clinicians to use.

a. Additional Adjustment Factors
Consistent with the statute, CMS proposes to apply a linear sliding scale where MIPS-eligible clinicians with a CPS at the additional performance threshold would receive 0.5 percent additional adjustment factor and MIPS-eligible clinicians with a CPS equal to 100 would receive a 10 percent maximum additional adjustment factor. Similar to the adjustment factor, CMS would apply a scaling factor that is greater than 0 and less than or equal to 1.0 if needed to ensure distribution of the $500 million increase in payments. CMS is proposing the starting point

for the additional adjustment factor at 0.5 percent for a CPS at the additional performance threshold, because CMS believes that this would provide a large enough incentive for MIPS-eligible clinicians to strive for the additional performance threshold, while still providing the opportunity for a positive slope on the linear sliding scale. If CMS is unable to achieve a linear sliding scale starting at 0.5 percent (because the estimated aggregate increase in payments for a year would exceed $500 million), then CMS proposes to lower the starting percentage for a CPS at the additional performance threshold until it is able to create the linear sliding scale with a scaling factor greater than 0 and less than or equal to 1.0.

AAFP Response
As noted, the agency's proposals related to the additional adjustment factors are consistent with the statute, so the AAFP supports them. We appreciate that CMS is proposing the starting point for the additional adjustment factor at 0.5 percent, if possible, rather than a lower percentage. However, CMS should be under no illusions that one half of one percent provides "a large enough incentive for MIPS-eligible clinicians to strive for the additional performance threshold."

8. Review and Correction of MIPS CPS
(1) Performance Feedback
(a) MIPS-Eligible Clinicians
(b) APM Entities
In these two sections, CMS first discussed the requirement that, at a minimum, the agency must provide MIPS-eligible clinicians with timely and confidential feedback on their performance under the Quality and Resource Use performance categories beginning July 1, 2017. They have discretion to provide such feedback regarding the CPIA and ACI performance categories. They will start in July 2017 with reports that are similar to the QRUR.

Since the first feedback report is due July 2017, prior to receiving any MIPS data, they propose to provide feedback to MIPS-eligible clinicians using historical data. The first report would contain data from CY 2015 or CY 2016 for Quality and Resource Use categories. In the event that 2017 is the first performance year for MIPS, which is what is currently proposed but not what the AAFP suggests, CMS would not anticipate getting MIPS data for feedback reports until 2018.
For the first year, feedback would be annual. In the future, this might evolve to quarterly.

AAFP Response
Feedback to clinicians needs to be provided in the form of reliable, real-time, patient-level data in order to make actionable improvement work possible. Since data from CY 2015 will be of minimal use to MIPS-eligible clinicians, data from 2016 should be the minimum standard. The AAFP would encourage CMS to provide feedback reports quarterly to MIPS-eligible clinicians as soon as is feasible. To improve quality and impact resource use in real time, real-time data is needed. If payment year 2019 is based on performance in 2017, quarterly reports in 2017 will be needed to affect any change to the MIPS score in 2019.

As to whether or not first year measures should be included in the feedback reports, the AAFP calls for all measures that are collected to be reported. The AAFP deduces that if a score is calculated and applied to an eligible clinician, CMS must have the infrastructure in place to make those calculations. Given that logic, it should be within the capability of CMS to generate feedback reports on all the categories that make up the CPS and have those reports distributed to MIPS-eligible clinicians. All MIPS-eligible clinicians will need data on all four performance categories starting in the first performance year. If eligible clinicians are to be "graded" in that

year, CMS should be accountable to report those grades. The feedback reports should include every field that will contribute to the score. If CMS cannot generate a feedback score, the program needs to be delayed until it is operational. Also, the ability to drill down on reports will be needed in order to make these reports actionable and individual physicians should be able to access their own reports and scorecards which is not the case with the current QRURs. Eligible clinicians must know their performance on all measures, including new measures, in order to improve outcomes.

(2) Mechanisms
CMS has the authority to provide feedback reports in one or more ways. For quality, if measures are reported through a registry, feedback will be provided based on performance on quality measures reported through the registry. For CPIA and ACI, CMS shall encourage feedback through a registry. The regulation discusses the agency's recognition that many eligible clinicians do not like the CMS portal currently in use for PQRS and QRUR, that many physicians do not know it is there, and then do not understand it if they find it. Therefore, CMS proposes to start with a similar web-based portal system, and, if technically feasible, an interactive dashboard. They will leverage health IT vendors, registries, QCDRs to disseminate data on measures where applicable.

CMS also points to physician feedback of which the organization was unaware at the time the PQRS report was made available and that the agency wants to use the information in PECOS to notify physicians, which would require all physicians to update their information.

AAFP Response
The AAFP does not believe the need exists to create a new feedback reporting system. CMS should focus on repairing the current system. CMS already asks much of clinicians, and clinicians could and should expect much in return from CMS. CMS should be held accountable just as they hold clinicians accountable. For instance, clinicians have deadlines for reporting, dates that must be met every year that are published and in statute and the AAFP calls on CMS to have the same type of deadlines. The AAFP suggests clinicians will know when to look for their reports if CMS is held accountable to provide all feedback reports on the same dates quarterly. The Quality, Resource Use, CPIA, and ACI reports should all be available in one location on the same day, therefore eliminating the administrative burden from the clinicians to gather their reports from multiple, hard-to-access, and hard-to-navigate websites and portals.

(3) Use of data
CMS discusses use of MIPS-eligible clinicians' data from periods prior to the current performance period, suggesting the organization may use rolling periods in order to make illustrative calculations about the performance of that professional. The agency discusses this would be a "dry-run" of the data including measure rates.

AAFP Response
If CMS is able to make "illustrative calculations" in advance of a performance year, they should have no problem providing eligible clinicians with feedback reports quarterly in advance of the performance year for all four performance categories.

(4) Disclosure Exemption
CMS proposes that feedback made available under MACRA shall be exempt from disclosure under the Freedom of Information Act.

AAFP Response
The AAFP concurs with this proposal.

(5) Receipt of Information
CMS expressed a desire to explore ways to receive information from clinicians and anticipates establishing a help desk or technical assistance area to address questions.

AAFP Response
The MIPS LEAN Design team from the CMS Quality Summit in December 2015 spent significant resources and time to identify approaches to streamlining data reporting, accessing reports and establishing help desk and technical assistance for providers, and we encourage CMS to re-visit these recommendations in the design of the information system. In particular, the MIPS LEAN team identified issues with the existence of multiple help desks, multiple CMS information systems that are not integrated, multiple log-ins, inability of first-line help desk personnel to address all but the simplest questions, contradictory responses from help desk personnel, long turn-around time for answers, and long telephone wait times. To remedy this, the AAFP supports a single access point and sign-on to all CMS systems that a clinician may need to access. We support offering multiple routes of assistance accessible from a single access point, including:

- a searchable knowledge database,
- phone support (with email documentation of responses) with a 24-hour turn-around window,
- immediate escalation if first-line help desk staff can't answer a question within 24 hours,
- email support with a 24-hour turn-around window, and
- live chat.

We also support maintaining a centralized, integrated database of question-and-response data that can be used to train help desk personnel, enrich the searchable knowledge database, and identify common areas of misunderstanding among clinicians for targeting program education. The AAFP supports creation of a dashboard for each physician/TIN that will allow he or she to review individual and/or group demographic information (including PECOS), data-submission status for the current reporting period, CPS, performance on all measures, feedback reports, and help desk access history, as well as other timely information that will help physicians better understand how quality reporting is impacting their Medicare reimbursement.

(6) Additional Information-Type of Information
MACRA states that by July 1, 2018, CMS shall make available to MIPS-eligible clinicians information about items and services for which payment is made under Title 18 to individuals who are patients of MIPS-eligible clinicians. This would include the name of who provided it, what was provided, when, and allowed charges.

AAFP Response
To improve the use of this information, the AAFP suggests that eligible clinicians looking to improve their resource use will find that information helpful. Other ways to make this information more robust would be alternatives to the items or services provided that would have been more cost effective for the patient, while still delivering the same quality of care. For example, if service A costs $100, that is fine to report. However, if the same report points out that same service is available from an equally qualified entity for $50, real change can be made. Taking

the burden of looking for alternatives off the clinician will lead to faster more substantial improvement.

b. Announcement of Result of Adjustments
According to MACRA, adjustments must be announced no later than December 1. CMS proposes to make the adjustment available on the performance feedback reports or through another mechanism.

AAFP Response
The AAFP suggests that with every feedback report released, a "proposed MIPS adjustment factor" should be included. This information would inform the eligible clinician about what his or her adjustment would be given their current performance state. An interactive tool allowing a clinician the chance to run a "what if" scenario regarding his or her adjustment would also be helpful. If the adjustment is negative, feedback reports need to be clear as to why. The report should provide clear information about the performance measure the upper and lower thresholds that would have resulted in the MIPS-eligible clinicians receiving a more positive and negative adjustments.

c. Targeted Review
MACRA requires a process to be established where MIPS-eligible clinicians may seek an informal review of the calculation of the MIPS adjustment factor. The circumstances under which a MIPS-eligible clinician may request a review are as follows:

- 1) The MIPS-eligible clinician believes the measures or activities submitted to CMS possess calculation errors or data quality issues.
- 2) The MIPS-eligible clinician believes CMS made errors such as wrongly assigning performance category scores (like not recognizing a low-volume threshold)

MIPS-eligible clinicians may submit a targeted-review request within 60 days after the close of the data submission period. All requests must be submitted by July 31 after the close of the data submission period or by a later date that they specify in guidance. A response with a decision on whether a targeted review is warranted will be provided. The timeline for review will vary based on the number of requests. If additional information is requested by CMS to conduct the review, the eligible clinician has 10 days to submit and the decision after the review is final.

AAFP Response
The window for submission of requests for targeted review should be based on when eligible clinicians receive their feedback from CMS, not 60 days from the close of data submission. Also, the process to submit an appeal should be easy, transparent and obvious to clinicians from the feedback report itself. If a clinician has 10 days to submit additional data (10 days is too short and 30 days is more reasonable), CMS should have some equally strict deadlines built into the scenario. We strongly encourage CMS to invest in creating an audit process that is timelier, eligible-clinician friendlier, and more predictable than we have seen with the EHR incentive program. We have heard horror stories from members about audits occurring many years after the attestation period. They tell us about short deadlines to justify findings of the audit contractor or to pay back incentive dollars. After re-prioritizing the work of the entire office to respond with the type of detailed information being requested, these members have found that their response goes into a black hole without getting any acknowledgement of receipt or information about when they could expect a response. A portion of those members then get a response from the contractor asking for more information about different components of the

attestation. For some, these issues devolve into a back-and-forth scenario; in each occurrence the member in question receives a demand for payment within a short time frame or to provide additional information. These experiences cannot occur again with the audits under MACRA.

e. Data Validation and Auditing
CMS proposes to combine past program integrity process of data validation from PQRS and auditing process from EHR incentive program into one set of requirements for MIPS-eligible clinicians and groups. They will selectively audit MIPS-eligible clinicians on a yearly basis. If selected, the eligible clinicians or group would be required to comply with data sharing requests within 10 business days and provide substantive, primary source documents as requested. If an eligible clinician or group is found to have submitted inaccurate data, CMS would recoup overpayments.

AAFP Response
The AAFP has no problem with the auditing process itself. However, we do call for clear deadline expectations to be set on both sides and insist that audit initiation be timely (within 12 months of the end of a performance year). Also, a 10-business-day deadline may not be feasible in all circumstances. CMS needs to factor in the possibility of vacation, sick leave, maternity care, etc. Thirty business days seems more reasonable. Clinicians also need to be provided clear examples of documentation well in advance of the submission deadline and technical assistance needs to be made available to help with the process.

9. Third-Party Data Submission
a. Qualified Clinical Data Registries (QCDRs), (3) Information Required at the Time of Self-Nomination and c. Qualified Registries (3) Information Required at the Time of Self-Nomination

In these two sections, CMS requests information required at the time of self-nomination for QCDRs and qualified registries. This includes a data validation plan for both individual eligible clinicians and groups, which meet the following: For individuals, it is encouraged that 3 percent of the TIN/NPIs submitted by the QCDR be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.

AAFP Response
It is important to note that requirements for data validation plans are sufficient to ensure accuracy of data, yet this requirement must be balanced with the burden of validation and auditing by the QCDR entity or qualified registry. We do not have sufficient information to comment on whether the proposed requirements are adequate to ensure data quality, nor can we comment as to whether the proposed requirements will be burdensome across various structures of QCDRs and registries. We hope CMS receives ample qualitative commentary in order to better judge whether the proposed numbers and percentages for validation plans strike an appropriate balance.

a. QCDRs, (4) QCDR Requirements for Data Submission, and c. Qualified Registries, (4) Qualified Registry Requirements for Data Submission
The rule proposes to require mandatory attendance of third parties for monthly support conference calls, as well as at the kick-off meeting in Baltimore, MD. More than one unexcused absence could result in the QCDR or registry being precluded from participation in the program for that year.

Regarding QCDR and qualified registry requirements for data submission, CMS also proposes QCDRs and qualified registries be required to obtain both the email addresses of eligible clinicians for the purpose of distributing performance feedback, as well as authorizations from each eligible clinician to release his or her email address.

AAFP Response
We presume that these ongoing monthly support conference calls will be highly beneficial for both QCDRs and qualified registries and that the majority of QCDR's will attend the calls more often than not. However, we do not endorse mandatory participation in these support calls, nor do we endorse mandatory in-person attendance at the QCDR kick-off meeting in Baltimore, MD, or the proposal that more than one unexcused absence could result in the QCDR or registry being precluded from participation in the program for that year. These proposals require unnecessary tracking efforts and create undue burden upon both QCDRs and qualified registries. The proposed data submission, validation, and ongoing auditing requirements are sufficient motivators to encourage QCDRs and qualified registries to utilize the support resources provided. In addition, absence from a mandated attendance conference call or meeting may have no bearing on the quality of the services the QCDR or qualified registry provides, yet could significantly harm the participating eligible clinicians should they no longer be able to use the QCDR or qualified registry simply due to lack of attendance at a meeting.

The AAFP strongly recommends that Direct addresses be utilized for trusted exchange of performance feedback information. Our recommendation is that it would be prudent to encourage use of the secure Direct exchange for this purpose between QCDRs, qualified registries, or any qualified third party, and its participating eligible clinicians.

a. QCDRs
(7) Collaboration of Entities to Become a QCDR:
The rule proposes to allow that an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR provided the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR (for example, September 1, 2016, to be eligible to participate for purposes of the 2017 performance period).

AAFP Response
The AAFP recommends the deadline for this be November 1 rather than September 1. November 1 is the deadline for self-nominations for QCDR and qualified registry status and is also the deadline for submission of all other information required as a component of the third-party qualification application process. For simplification and standardization, we recommend November 1 be established as the deadline for the written agreement between an entity and an external organization that will perform data collection, calculation, or transmission in order to meet the definition of a QCDR.

c. Qualified Registries
(1) Establishment of an Entity Seeking to Qualify as a Registry
The rule proposes (at §414.1400(h)) that in order for an entity to become qualified for a given performance period as a qualified registry, the entity must be in existence as of January 1 of the performance period for which the entity seeks to become a qualified registry (for example, January 1, 2017, to be eligible to participate for purposes of performance periods beginning in

2017). The qualified registry must have at least 25 participants by January 1 of the performance period.

AAFP Response
The 25-participant requirement to become a qualified registry seems arbitrary. We would have concerns for new entries of Qualified Registries and also do not feel participants should be required to be in place by January 1. As qualified registries have the potential to pull historical data, we believe there should not be a deadline before the end of the reporting period. Removing both the 25-participant limit and the early deadline would ensure eligible clinicians have maximum choice in selecting the right qualified registry for them. With this proposed change, there becomes a need for clear and honest marketing by eligible qualified registries. We ask that CMS require eligible qualified registries to provide clear information to potential eligible clinician clients about their current recognition status with CMS.

e. Probation and Disqualification of a Third Party Intermediary
CMS proposes a third-party may be placed on probation at any time it is determined the party fails to meet all requirements of qualification to submit performance data. Upon notification of deficiencies or probation, the third party must submit and receive approval of a corrective action plan within 14 days. Failure to submit a corrective plan within 14 days or correct deficiencies within 30 days may result in disqualification from MIPS for the current and subsequent performance periods. No absences from what are proposed to be mandatory meetings would be permissible. Poor data quality submissions will result in public posting of such on the CMS list of qualified third parties, and persistence of data quality issues or probation of 2 years can result in disqualification.

AAFP Response
Regarding probation and disqualification of a third-party intermediary, the AAFP agrees that, with the exception of mandatory attendance at conference calls and meetings, the outlined details surrounding probation and disqualification sound reasonable. Namely, responsiveness to CMS with a proposed corrective action plan within 14 days of notification and cooperative efforts toward remediation or correction of deficiencies identified sound reasonable. As previously noted, we do not support mandatory attendance for conference calls and meetings. As well, we feel strongly that the final rule should be comprehensive and prescriptive in regard to third-party probation and disqualification, not only in terms of how the third party is to be handled and expected to respond, but also in terms of how the users (i.e., the eligible clinician participants) of those third-party services should be handled, in regard to their inability to report performance data under these circumstances. Because reporting of performance data is a requirement for MIPS, it is prudent to incorporate, within this section of the final rule, language that holds eligible clinicians harmless for suspension or disqualification of third-party intermediaries contracted for the purpose of submission of performance data.

10. Public Reporting on Physician Compare
CMS proposes a 30-day preview period in advance of the publication of any data on Physician Compare. All data available for public reporting, measure rates, scores, and/or attestations, will be available for review and correction during the targeted review process. Data under appeal and review will not be publicly reported until the review is complete.

CMS also proposes public reporting of an eligible clinician's MIPS data; in that for each program year, CMS would post on a public website, in an easily understandable format, information regarding the performance of MIPS-eligible clinicians or groups under the MIPS. Specifically,

CMS proposes inclusion of the information described in sections (a) through (g) on Physician Compare.

AAFP Response
We support transparency in reporting and welcome the opportunity to review any and all data posted to Physician Compare. As noted in our comments on the proposed 2016 Medicare physician fee schedule and our letter in response to the MACRA RFI, we are supportive of the Physician Compare concept, but have several concerns regarding the complexity and accuracy of the information and its usefulness to consumers. It is increasingly important for CMS to address these concerns, given that MACRA expands the use of the Physician Compare website.

For instance, while CMS has mechanisms in place to ensure the data is valid, reliable, and correctly attributed, errors still persist. Because of this, the AAFP urges CMS to extend the current preview period from 30 to 90 days at a minimum. This will give the physician sufficient time to review, validate, and appeal before public reporting of his or her data. We agree with CMS that if information is under review or appeal, it should not be publicly reported on the website until the issues are resolved. Once the data is publicly available, a downloadable, delimited file (that also includes NPIs) should also be made ready for use.

a. Composite Score, Performance Categories, and Aggregate Information
Consistent with the law, CMS proposes—to the extent that they meet the previously established public reporting standards—that the following data will be added to Physician Compare for each MIPS-eligible clinician or group, either on the profile pages or in the downloadable database, as technically feasible:

- the composite score for each MIPS-eligible clinician;
- performance of each MIPS-eligible clinician for each performance category; and
- aggregate information on the MIPS, including the range of composite scores for all MIPS-eligible clinicians and the range of performance of all the MIPS-eligible clinicians for each performance category.

Statistical testing and consumer testing, as well as consultation of the Physician Compare Technical Expert Panel (TEP), will determine how and where these data are reported on the website. CMS requests comments on these proposals and on the advisability and technical feasibility of including data voluntarily reported by eligible professionals and groups that are not subject to MIPS payment adjustments, such as those practicing through RHC or FQHCs on Physician Compare.

AAFP Response
What CMS proposes is consistent with the statute, and we support its intent to implement the law, as technically feasible, after doing appropriate statistical and consumer testing and consulting with the Physician Compare TEP. We believe that if eligible clinicians and groups voluntarily choose to report data, their data can be subsequently reported on Physician Compare, as long as the eligible clinicians and groups understand that is a consequence of voluntary reporting before they report the data.

b. Quality
CMS proposes to make all measures under the MIPS quality performance category available for public reporting on Physician Compare. This includes all available measures reported via all

available submission methods, and applies to both MIPS-eligible clinicians and groups. Although all measures will be available for public reporting, not all measures will be made available on the consumer-facing website profile pages. Instead, CMS proposes that all measures in the quality performance category that meet the public reporting standards would be included in the downloadable database, as technically feasible. CMS proposes that only a subset of these measures would be publicly reported on the website's profile pages, as technically feasible. Statistical and consumer testing will determine how and where measures are reported on Physician Compare. CMS notes that they do not publicly report first-year measures, so after a measure's first year in use, CMS will evaluate it to gauge whether or not the measure is suitable for public reporting.

There is currently a minimum sample size requirement of 20 patients for performance data to be included on the website. CMS proposes to institute a minimum reliability threshold for public reporting on Physician Compare.

CMS also proposes to include the total number of patients reported on per measure in the downloadable database to facilitate transparency and more accurate understanding and use of the data. CMS seeks comment on the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the quality performance category.

AAFP Response
The AAFP supports the agency's intent that only a subset of the quality measures will be publicly reported on the website's profile pages as technically feasible, after doing appropriate statistical and consumer testing. Too many measures published on Physician Compare are likely to confuse rather than inform Medicare beneficiaries. In particular, we recommend that CMS publicly report only those measures used to score the individual eligible clinician under MIPS.

The AAFP also supports the proposal to institute a minimum reliability threshold for public reporting on Physician Compare. As noted in the AAFP's response to the MACRA RFI, the AAFP prefers the use of a minimum reliability threshold instead of a minimum patient threshold. As highlighted in the AAFP's Guiding Principles on Physician Profiling, we believe that the validity, accuracy, reliability, and limitations of data used are important when reporting profiling results and providing physician feedback. Consistent with our Guiding Principles on Physician Performance Reporting, we also believe that it is important to be transparent in the number of cases assessed per measure. However, as far as a threshold for reporting is concerned, we believe that reliability is superior to a simple, arbitrary number of patients. For perspective on this issue, we would also refer CMS to our policy on Performance Measures Criteria.

With respect to the types of data that should be reported on Physician Compare as the MIPS program involves—specifically regarding the Quality Performance category—we recommend CMS include the measure description and performance along with the applicable benchmark and range of scores. Once the data is publicly available, a downloadable, delimited file (that includes NPIs) should also be made available.

c. Resource Use
CMS proposes to make all measures under the MIPS Resource Use category available for public reporting on Physician Compare. This includes all available measures reported via all available submission methods, and applies to both MIPS-eligible clinicians and groups.

Although all measures will be available for public reporting, not all measures will be made available. Instead, CMS proposes that only a subset of these measures would be publicly reported either on the website's profile pages or in the downloadable database, as technically feasible. Statistical and consumer testing will determine how and where measures are reported on Physician Compare. CMS notes that they do not publicly report first-year measures, so after a measure's first year in use, CMS will evaluate it to gauge whether or not the measure is suitable for public reporting. CMS seeks comment on the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the Resource Use category.

AAFP Response
The AAFP supports the agency's intent that only a subset of the Resource Use measures will be publicly reported as technically feasible, after doing appropriate statistical and consumer testing. Too many measures published on Physician Compare are likely to confuse rather than inform Medicare beneficiaries. Appropriate statistical and consumer testing needs to be done in all types of markets: urban, suburban, and rural.

With respect to the types of data that should be reported on Physician Compare as the MIPS program evolves—specifically regarding the resource utilization category—we note a wide array of possibilities, including but not limited to: visits, procedures, episodes (based on CMS' final rule on which ones they'll measure), laboratory services, diagnostic tests, imaging, and drugs. We believe it is likely the public will be interested in the total risk-adjusted cost of care for specific types of procedures—inpatient/ambulatory surgery/outpatient—including facility and physician costs.

If CMS goes forward, the information needs to be presented to the public in a simple format that is paired with a massive education campaign in order for the populace to understand this information. One idea is to combine cost and quality into a merged score of some sort.

In any case, the volume of data should not act as a deterrent to making it publicly available apart from the Physician Compare website if there is a robust user interface to run cost and resource utilization queries. While consumers' use of that data may be limited, making it public is still a beneficial service.

d. CPIA
CMS proposes to make all activities under the MIPS CPIA performance category available for public reporting on Physician Compare. This includes all CPIA reported via the available submission methods and applies to both MIPS-eligible clinicians and groups. Although all measures will be available for public reporting, not all measures will be reported. Instead, CMS proposes that only a subset of CPIA data would be publicly reported either on the website's profile pages or in the downloadable database, as technically feasible. Statistical and consumer testing will determine how and where measures are reported on Physician Compare. For those eligible clinicians that successfully meet the CPIA performance category requirements, this may be posted on Physician Compare as an indicator. CMS notes that they do not publicly report first-year measures, so after a measure's first year in use, CMS will evaluate it to gauge whether or not the measure is suitable for public reporting.

CMS seeks comment on the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the CPIA performance category.

AAFP Response
The AAFP supports the agency's intent that only a subset of the CPIA data would be publicly reported as technically feasible, after doing appropriate statistical and consumer testing. Too many measures published on Physician Compare are likely to confuse rather than inform Medicare beneficiaries.

With respect to the types of activities that should be reported on Physician Compare as the MIPS program involves, specifically in regard to the CPIA category, we support the idea of listing the score at the practice level with an explanation of what this category entails. CMS should not list individual activities being done by each practice, as such a list would only capture those activities claimed for MIPS, and not all activities, which may be much more extensive.

e. Advancing Care Information
Since the beginning of the EHR Incentive Programs in 2011, participant performance data has been available in the form of public use files on the CMS website. At this time, there is only a green check mark on Physician Compare profile pages to indicate that an EP successfully participated in the current Medicare EHR Incentive Program for EPs. CMS is proposing to include more information on eligible clinician's performance on the objectives and measures of meaningful use on Physician Compare. Specifically, CMS is proposing to include an indicator for any eligible clinician or group who successfully meets the ACI performance category, as technically feasible, on Physician Compare. CMS is also, as technically feasible, proposing to include additional indicators, including but not limited to, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange. Any ACI objectives or measures must meet the public reporting standards to be posted on Physician Compare, either on the profile pages or in the downloadable database. Statistical testing and consumer testing will determine how and where objectives and measures are reported on Physician Compare. CMS notes that they do not publicly report first year measures, so after a measure's first year in use, CMS will evaluate it to gauge whether or not the measure is suitable for public reporting.

CMS is also seeking comment on potentially including an indicator to show low performance in the ACI performance category, as well as the types of data that should be reported on Physician Compare as the MIPS program evolves, specifically in regard to the ACI performance category. This would be subject to consumer and feasibility testing, if pursued.

AAFP Response
The performance on some of the measures under ACI depends heavily on the needs and desires of the patient population for which a physician practice cares. For example, a physician that has a very large senior population may have a very low "secure messaging with patients" measure. That value may or may not reflect the physicians' performance on secure messaging with patients that desire to use the tool. Accordingly, we believe it is too early to proceed down the road that CMS is proposing to travel, and we urge caution in public reporting of these data. Instead, we recommend that CMS only include a check to indicate whether a physician is using CEHRT, similar to what it does now in posting a green check mark on Physician Compare profile pages to indicate that an eligible professional successfully participated in the current Medicare EHR Incentive Program.

f. Utilization Data
CMS previously finalized policy to begin to include utilization data in the Physician Compare downloadable database in late 2016 using the most currently available data to meet section

104(e) of the MACRA and that not all available data will be included. The specific codes included will be determined based on analysis of the available data, focusing on the most-used codes. The goal will be to include counts that facilitate a greater understanding and more in-depth analysis of the other measure and performance data being made available. CMS proposes to continue to include utilization data in the Physician Compare downloadable database.

AAFP Response
What CMS proposes is consistent with the requirements of section 104(e) of MACRA. The AAFP does not object to including appropriate utilization data in the Physician Compare downloadable database, since the data is otherwise available through other sources on the CMS website.

g. APM Data
Currently, if an EP or group submitted quality data as part of an ACO, there is an indicator on the eligible professional's or group's profile page denoting this. Also, all ACOs currently have a dedicated page on the Physician Compare website to showcase their data. If technically feasible, CMS proposes to use this model as a guide while they add APM data to Physician Compare. CMS proposes to indicate on eligible clinician and group profile pages when the eligible clinician or group is participating in an APM. CMS also proposes to link eligible clinicians and groups to their APM's data, as relevant and possible, through Physician Compare. Data posting would be considered for both Advanced and non-eligible APMs.

AAFP Response
What CMS proposes is consistent with what the law requires. Using the current approach for reporting ACO involvement as a model for reporting APM involvement makes sense. We appreciate that data posting would be considered for both Advanced and non-eligible APMs.

F. Overview of Incentives for Participation in Advanced Alternative Payment Model
3. Terms and Definitions
CMS proposes the term "Advanced APM" for those APMs defined by section 1833(z)(3)(C) of the Act that meet the criteria under section 1833(z)(3)(D) of the Act. CMS uses the term "Advanced" in lieu of "Eligible."

Similarly, CMS proposes to use the term "Advanced APM Entity" instead of "alternative payment entity." CMS proposes that an APM Entity would be any participating entity in an APM, whereas an Advanced APM Entity would be one that participates in an APM that CMS has, in fact, determined to be an Advanced APM.

CMS proposes to define the terms "Medical Home Model" and "Medicaid Medical Home Model" as subsets of APMs and Other Payer APMs, respectively. CMS notes that medical homes would be the APM Entities in an APM, not the APM itself.

CMS proposes that a Medical Home Model must have the following elements at a minimum:

- Model participants include primary care practices or multispecialty practices that include primary care physicians and clinicians and offer primary care services.
- Empanelment of each patient to a primary care clinician.

In addition, CMS proposes that a Medical Home Model must have at least four of the following elements:

- Planned coordination of chronic and preventive care.
- Patient access and continuity of care.
- Risk-stratified care management.
- Coordination of care across the medical neighborhood.
- Patient and caregiver engagement.
- Shared decision-making.
- Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings, population-based payments).

CMS believes that an APM cannot be a Medical Home Model unless it has a primary care focus with an explicit relationship between patients and their practitioners. To determine that an APM has a primary care focus, CMS proposes that the Medical Home Model would have to involve specific design elements related to Eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant. CMS solicits comments on whether this proposal for determining that an APM has a primary care focus is sufficiently specified.

Finally, CMS seeks comment on these elements and which of the elements should be required as opposed to optional. CMS's proposed definition of Medicaid Medical Home Model is identical to Medical Home Model, except that it specifically describes a payment arrangement operated by a State under title XIX.

AAFP Response
Regarding CMS's proposal to use "Advanced APM" in lieu of "Eligible APM" for those APMs defined by section 1833(z)(3)(C) of the Act that meet the criteria under section 1833(z)(3)(D) of the Act, we are indifferent. The proposed use of the term "Advanced APM Entity" seems similarly straightforward, as is the distinction that CMS draws between the terms "APM Entity" and Advanced APM Entity."

The distinction between Medical Home Models as APMs and medical homes as APM entities is a particularly fine one that may be lost on most physicians. Given the elements that CMS proposes to require for a "Medical Home Model," it may make more sense to describe such APMs as "Primary Care-Focused Models" and to better-connect that term to the "medical home" description by incorporating the latter term in the proposed required elements. For instance, CMS could state that Primary-Care-Focused Model participants must include "primary care medical home practices or multispecialty practices that provide medical homes staffed by primary care physicians that offer primary care services."

Whether CMS calls such APMs "Medical Home Models" or "Primary Care-Focused Models," we agree with the intent of CMS's proposal to require primary care as an essential element. In fact, we would encourage CMS to take this proposal a step further and strengthen its proposed essential elements along the following lines:

- Model participants are either primary care medical home practices or multispecialty practices that provide medical homes staffed by primary care physicians and offer primary care services.
- Empanelment of each patient to a primary care physician.

We agree with CMS that an APM cannot be a Medical Home Model (or Primary Care-Focused Model) unless it has a primary care focus with an explicit relationship between patients and their primary care physicians. In this context, we suggest CMS limit its definition of eligible clinicians to those practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 37 Pediatric Medicine; and 38 Geriatric Medicine.

We have concerns about CMS's proposal to include eligible clinicians under one or more of the following specialty codes: 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant. These health care professionals are not always primary care providers. Under CMS's proposal, it seems theoretically possible that a surgical subspecialist who employed one or more of these clinician types could claim to have a primary care focus under a "Medical Home Model." Such an arrangement would be a bastardization of the term "primary care," in our opinion. Furthermore, the Joint Principles of the Patient-Centered Medical Home—developed by the AAFP, the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American Osteopathic Association (AOA)—include "Physician-directed medical practice." Potentially relying on eligible health care professionals such as nurse practitioners and physician assistants without the involvement of a primary care physician is contrary to the joint principles.

With respect to the optional elements proposed by CMS, at least four of which a Medical Home Model must have, we note that the following joint principles are missing from the list:

- Whole Person Orientation
- Quality and Safety

We would encourage the addition of these elements to the list proposed by CMS so that the CMS definition of the Medical Home Model is more in line with the Joint Principles of the Patient-Centered Medical Home and the five key functions of the CPC initiative. The AAFP believes those principles and key functions best define advanced primary care practices.

Finally, we agree with CMS's proposal to make these additional elements optional and permit a Medical Home Model to have just four of them.

(4) Advanced APMs
(a) Advanced APM Determination
CMS proposes to establish a process to identify and notify the public of the APMs that would be considered Advanced APMs. Such notification would be posted prior to the beginning of the first QP Performance Period and updated on a rolling basis. The initial set of Advanced APM determinations will be released no later than January 1, 2017. Determinations for new APMs will be included with the first public notice of the model. These determinations would be posted on the CMS website and updated on an ad hoc basis, but no less than annually.

AAFP Response
The AAFP urges CMS to announce the initial set of Advanced APM determinations within the final MACRA rule that is released later this year, if not earlier. Waiting until January 1, 2017, further delays practices' ability to make their decisions regarding potential participation in an Advanced APM. We also ask CMS to update their website at least every six months to allow physicians to make informed decisions on a more predictable basis.

(1) Use of Certified EHR Technology
To be considered an Advanced APM, the first criterion an APM must meet is the use of CEHRT by its participants. For Advanced APMs and Other Payer Advanced APMs, CMS proposes to adopt the definition of CEHRT that is proposed for MIPS and the APM incentive under §414.1305.

While the statute does not specify the number of eligible clinicians within the Advanced APM who must use CEHRT, CMS feels it has the discretion to define this requirement. CMS proposes that an Advanced APM must require at least 50 percent of its eligible clinicians who are enrolled in Medicare to use certified health IT functions to document and communicate with patients and other health care professionals. CMS proposes that this threshold will apply only to the first QP Performance Period. Beginning with the second QP Performance Period, CMS proposes to increase the threshold to 75 percent. CMS reiterates that the agency will not assess each individual eligible clinician or APM Entity, but rather will determine whether the APM's requirements meet the proposed thresholds. CMS seeks comment on the thresholds for the use of CEHRT by APM Entities.

CMS proposes an alternative criterion that applies to the Medicare Shared Savings Program (MSSP). While the MSSP does not require a specific level of CEHRT use, it does include an assessment of EHR use as part of the quality performance standard. In order to adopt a consistent CEHRT eligibility standard for the MSSP and other APMs, CMS would be required to undertake significant rulemaking. As such, CMS proposes to allow the MSSP to meet the CEHRT criterion by continuing to hold APM Entities accountable for their eligible clinicians' use of CEHRT by applying a financial reward or penalty based on the degree of use.

CMS also seeks comments on other health IT functionality that APM participants might need.

Finally, CMS is interested in receiving feedback on whether new health IT standards and certification criteria may be needed to ensure access to products and necessary services. They intend to work with the Office of the National Coordinator for Health Information Technology (ONC) to explore ways that the definition of CEHRT can meet the needs of APM participants while also supporting eligible clinicians participating in the MIPS. CMS notes there is a growing focus on facilitating health information exchanges (HIEs) among health care professionals at various levels.

AAFP Response
Use of CEHRT should not be based on a utilization threshold. An Advanced APM's attestation of adoption of CEHRT should be sufficient to meet statutory requirements. Due to reasons outlined in our comments on the ACI section of the rule, we disagree that certified health IT utilization measures will be useful in achieving the desired goals. Health IT adoption is well underway and serves as the only means of achieving desired outcomes that value-based payment and advanced alternative payment models reward. Thus, it is time to move beyond measuring the utilization of CEHRT. Investing time and resources into defining and measuring CEHRT utilization thresholds is simply wasteful. Under current law, CMS cannot completely abandon health IT utilization measures, but we believe that CMS can make significant improvements and reduce administrative complexity and burden while complying with current law. Relying on attestation is a step in the right direction.

Regarding the proposal to allow the MSSP to meet the CEHRT criterion, the AAFP believes attestation should be the methodology to assess the CEHRT use, as noted previously.

Regarding other health IT functionality, the AAFP believes health IT should support the following:

- Empanelment of patients to clinicians and/or care teams
- Empanelment of patients to registries
- Risk stratification of patient populations
- Display of eCQM results by provider, as well as by practice site address and TIN to support the Triple Aim (with ability to empanel providers to specified provider groups)
- Secure messaging via Direct exchange with any provider, health system, or patient with a Direct address
- EHR tracking of non–office-based care provision (e.g., emails, telehealth and telemedicine interactions, telephone encounters, text reminders, letters)
- Registry functionality
- Effective integration of lifestyle and preferences data, including data contributed via patient-generated health data (PGHD)
- Data-handling functionality for PGHD that is initially sequestered but offers ability to promote to various areas within the EHR and accompanied by metadata including source attribution/data provenance
- Effective integration of socioeconomic determinants of health data
- Team-based care functionality (e.g., task management, results and therapy management, shared care planning)
- Collaborative care planning functionality
- Integration of externally exchanged information into the EHR, with data provenance information retained to distinguish between internal and external data
- Streamlined medication reconciliation functionality
- Access to each patient's payer- and plan-specific formulary and cost data to support medical decision making at the point of care

This list of additional health IT functionality is illustrative, not exhaustive. Family physicians need functionality that allows them to easily improve the following: access to care; care coordination; patient engagement; evidence-based shared medical decision making; individual and care team results management; individual patient outcomes; and population health. Health IT functionality should also enable elimination of waste and containment of costs.

Regarding new health IT standards, the AAFP is supportive of more certification requirements and testing around interoperability. However, we continue to believe that meeting health IT utilization measures should not be required, even for HIEs.

(2) Comparable Quality Measures
The second Advanced APM criterion is that the APM must provide payment for covered professional services based on quality measures comparable to those under the performance category described in section 1848(q)(2)(B)(i) of the MACRA. CMS's proposed policy for this criterion is based on the proposed policy for the MIPS Quality performance category. CMS believes Advanced APMs should have the flexibility to select measures that appropriately meet their needs.

CMS proposes that Advanced APM quality measures must include at least one of the following types of measures:

- Any quality measures included on the proposed annual list of MIPS Quality measures
- Quality measures that are endorsed by a consensus-based entity
- Quality measures developed under section 1848(s) of the MACRA
- Quality measures submitted in response to the MIPS Call for Quality Measures
- Any other quality measures that have an evidence-based focus and are reliable and valid, per CMS assessment

Measures developed by the National Quality Forum (NQF) will meet these criteria. QCDR measures will be considered MIPS-comparable measures. For measures that are not NQF-endorsed or included on the final MIPS list, CMS proposes to establish a Center for Medicare & Medicaid Innovation review process to assess whether a quality measure has an evidence-based focus, and is reliable and valid. As a priority domain under the MIPS, CMS proposes that an Advanced APM must also include one outcome measure, if an appropriate measure is available on the MIPS list.

AAFP Response
The AAFP strongly 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 core measure sets contain a variety of measure types. Use of these sets reduces administrative burden. In addition, the use of consistent measures will provide an easy on-ramp for providers participating in the MIPS who transition to APMs.

The AAFP asks CMS to urge private payers to adopt the core measures sets in order to create a sense of stability between the public and private payer realms. APMs will be able to prioritize measures more easily if a standard set of measures is used by CMS and private payers.

The AAFP is concerned that CMS proposes establishing yet another process for assessing quality measures. CMS should continue to use the established processes and criteria to determine if a measure is evidence-based, reliable, and valid. We believe CMS can leverage the NQF's MAP process as a means of accomplishing this. The creation of a new process could slow down an already lengthy process, leading to the implementation of measures that are outdated or have little clinical relevance. In addition, the AAFP is concerned that a new process could lack key elements; for example, the MAP process incorporates invaluable input from practicing physicians. The AAFP encourages CMS to include updated core measures as they become available.

The AAFP believes specialists should not be exempt from the outcome measure requirement. Therefore, all Advanced APMs, regardless of specialty, should be required to include an outcome measure. If an outcome measure is not available for a specific specialty, then the specialty society should be responsible for creating one.

(3) Financial Risk for Monetary Losses
(a) Overview
The third Advanced APM criterion requires the APM to either:

- Be a Medical Home Model that is expanded under section 1115A(c) of the MACRA, or
- Bear financial risk for monetary losses that exceed a nominal amount

CMS proposes that this financial risk criterion for Advanced APMs will apply to the design of the financial risk arrangement between CMS and the APM Entity.

To account for differences in Advanced APMs, CMS proposes two sets of financial risk standards: standards for a Medical Home Model and a set of generally applicable standards.

As proposed by CMS, the Medical Home Model standards will include limitations on size and composition. Beginning in the second QP Performance Period, the Medical Home Model standards for financial risk and nominal risk would apply only to Medical Home Models with APM Entities that have 50 or fewer eligible clinicians in the organization that owns and operates the entity. CMS feels it is necessary to impose this limitation to ensure focus on small organizations that are not able to assume the same amount of risk as larger organizations. CMS believes that an organization with more than 50 eligible clinicians can take on more risk. CMS's goal is to encourage larger organizations to move into Medical Home Models with higher risk levels. If an organization meets the generally applicable standards, the size limitation would be moot. CMS seeks comment on this proposal.

AAFP Response
The AAFP adamantly opposes this CMS-proposed financial standard for the Medical Home Model. The AAFP views this as an egregious misinterpretation of the law, which was designed to protect and foster medical homes. The financial standard for the Medical Home Model arbitrarily imposes financial risk upon clinicians in these models and violates the intent of the law.

The medical home is the cornerstone of a value-based health care system. In *The Patient-Centered Medical Home's Impact on Cost and Quality: Annual Review of the Evidence, 2014-2015*, the Patient-Centered Primary Care Collaborative identified several PCMH programs that have reduced costs and improved quality. The review found that 21 of 23 PCMH programs reporting on cost measures had reductions in one measure or more, and 23 of 25 PCMH programs reporting on utilization measures had reductions in one measure or more.

Medical homes are a foundational element of health system transformation, and, because of their importance to the success of the value-based payment model, they are protected under the law from assuming risk. CMS's proposal removes provisions of the law that create a safety net for medical homes. In addition, spending and utilization are reduced in a PCMH, so imposing risk sharing on the Medical Home Model may be counterproductive and discourage adoption of this model. To foster an environment in which medical homes can succeed, the AAFP strongly believes that medical homes should not be subject to any financial risk and that CMS should remove the Medical Home Model financial standard in its entirety from the proposed rule.

(b) Bearing Financial Risk for Monetary Losses
(i) Generally Applicable Advanced APM Standard
CMS proposes a generally applicable financial risk standard for Advanced APMs that do not meet the size-limitation criterion for the Medical Home Model. Under this financial standard, if actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified performance period, CMS can do the following:

- Withhold payment for services to the APM Entity and the APM Entity's eligible clinicians

- Reduce payment rates to the APM Entity and the APM Entity's eligible clinicians
- Require the APM to owe payments to CMS

CMS notes that financial risk must be tied to performance as opposed to indirect losses related an APM Entity's financial investments.

AAFP Response
We feel the proposed financial risk standard is overly complex, and we urge CMS to simplify it. For example, the AAFP recommends that CMS should reduce payments over a calendar year if either:

- Actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a performance period; OR
- The APM entity's performance on specified measures does not meet or exceed performance for a specified period.

We believe these options will help reduce the potential burden of requiring entities to pay CMS a lump sum amount. The AAFP represents many independent family physicians. These family physicians are not part of a larger system, therefore making it possible that they will comprise the entire APM Entity. Requiring such a practice to pay may be difficult as they have small operating margins and little to no reserves available. Additionally, withholding payment for services already rendered not only disincentivizes physicians from providing services for which they know they will not receive payment, but it places a strain on practices that count on such payments to meet payroll and other financial obligations.

The AAFP continues to believe family physicians already have risk associated with their own operating expenses. CMS should continue to investigate ways in which to incorporate investment risk into the financial risk for monetary losses standards.

(ii) Medical Home Model Standard
For a Medical Home Model to be an Advanced APM, it must include provisions that potentially:

- "Withhold payments for services to the APM Entity and the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and the Entity's eligible clinicians
- Require the APM Entity to owe payments to CMS; or
- Lose the right to all or part of an otherwise guaranteed payment or payments if either:
- Actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified reporting period; or
- APM Entity performance on specified performance measures does not meet or exceed expected performance on such measures for a specified performance period."

AAFP Response
The AAFP adamantly opposes this CMS proposed financial standard for the Medical Home Model. The AAFP views this as an egregious 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. Therefore, the AAFP strongly believes CMS should remove the Medical Home Model financial standard in its entirety from the proposed rule and Medical Homes should not be subject to any financial risk.

CMS states that they view organizations with more than 50 eligible clinicians as the appropriate threshold because organizations of such a size have demonstrated the capability and interest in taking on higher levels of two-sided risk. The AAFP remains unclear as to how CMS determined 50 ECs was the appropriate number for this threshold. An arbitrary threshold should not be used when determining the amount of financial risk an entity can assume. The assumption of risk should not be determined by a general threshold number of ECs within the organization, rather it should be based on each entity's demonstrated capabilities. Taking on financial risk of any amount is a decision that is not taken lightly by the entities. CMS should afford the entities the same courtesy and develop an appropriate way to determine if an entity is capable of taking on risk. CMS proposes to remove the provisions of the law that were placed there to provide a safety net for small and solo practices and which were designed to help these practices succeed under value-based payment. To foster an environment in which a small or solo physician can succeed, CMS needs to remove this provision.

(4) Nominal Amount of Risk
(a) Advanced APM Nominal Amount Standard
CMS interprets the meaning of "nominal" to mean minimal in magnitude; however, they do not believe the assumption of nominal risk is a formality and should therefore be a meaningful amount. To develop their proposal, CMS reviewed MIPS adjustments and current APM risk arrangements, including Tracks 2 and 3 of the SSP, the Pioneer ACO, and Bundled Payments for Care Improvement Initiative (BCPI). The APM risk amounts are designed to motivate the changes in practices that will reduce costs and improve quality.

APMs where the generally applicable financial standards apply will be need to meet three dimensions of nominal risk to be considered an Advanced APM. First, an APM must contain marginal risk. CMS proposes that marginal risk must be at least 30 percent of losses in excess of expected expenditures. The second dimension of risk is a minimum loss rate (MLR). This must be no greater than 4 percent of expected expenditures. Finally, CMS proposes an APM must include total potential risk of at least 4 percent of expected expenditures. Expected expenditures will be defied by the level of expenditures in the APM's benchmark. In an episode payment model, expected expenditures would be reflected in the target price.

CMS proposes a process by which they would determine a risk arrangement to satisfy the nominal risk requirements with an MLR higher than 4 percent, provided that the other portions of the standard are met. CMS would take into consideration the size of the attributed population, the relative magnitude of the expenditures, and whether the difference between actual and expected expenditures would not be statistically significant. These exceptions would be granted on rare occasions.
Payments made outside the risk arrangement related to expenditures would not count towards the nominal risk standard. CMS requests comments on appropriate levels on the Advanced APM nominal amount standard.

AAFP Response
The AAFP believes the nominal risk standard as proposed by CMS is complicated and confusing. Eligible clinicians need to be able to understand the amounts of risk they are being asked to assume. Requiring an eligible clinician to become an actuary to understand this regulation is unrealistic. Such a structure will function as a deterrent to eligible clinicians wishing to join an APM entity. There is a vast amount of variability in the risk arrangements this structure could create. A physician who joins an APM with a complex risk arrangement they are unable to understand will set them up for failure.

The AAFP encourages CMS to simplify the standard for nominal risk amount to include only the minimum loss rate (MLR) and total potential risk requirements proposed in the regulation. We believe marginal risk introduces an unneeded level of complexity to the nominal risk standard and do not view it as necessary. The total potential risk should be sufficient to meet the nominal risk requirement of the law and is the key measurement of risk. The AAFP believes the MLR is an important component to insure risk is not being triggered by chance. We ask that CMS modify the total potential risk and base it on an entity's Part A and B revenue to provide the assurance that an entity is not assuming more risk than their potential revenues. Entities of all sizes will be able to assume varying levels of risk. It is critical that CMS ensures the success of these entities by allowing for risk structures that will support this success.

(b) Medical Home Model Standard
CMS proposes a separate nominal risk amount standard for Medical Home Models who meet the corresponding financial risk standards. CMS feels Medical Home Models operate in a unique setting that warrants a nominal risk standard that addresses their lack of experience with risk. As proposed, Medical Home would be required to take on risk based on Medicare Parts A and B revenue, rather than having their risk based on benchmarks that incorporate total cost of care. An APM entity could potentially owe CMS or forego must be at least:

- 2017 – 2.5 percent of Entity's total Medicare Parts A and B revenue
- 2018 – 3 percent of Entity's total Medicare Parts A and B revenue
- 2019 – 4 percent of Entity's total Medicare Parts A and B revenue
- 2020 and beyond – 5 percent of Entity's total Medicare Parts A and B revenue.

AAFP Response
The AAFP strongly believes this provision should be removed from the proposed rule as the law did not intend for Medical Homes to assume risk of any amount. Medical Homes were intended to be a protected group under the law.

We reiterate our steadfast opposition to the Medical Home Model financial risk and the Medical Home Model nominal amount standards. Both provisions need to be removed from the program.

(5) Capitation
CMS proposes that full capitation risk arrangements would meet the Advanced APM financial risk criterion. For the purposes of this rule, a capitation risk arrangement means an arrangement in which a per capita or predetermined payment is made to an APM Entity for all items and services furnished to beneficiaries without a reconciliation process or sharing losses incurred or savings earned by the Entity. CMS distinguishes between capitation as a risk arrangement from capitation as only a cash flow mechanism. Capitation as only a cash flow mechanism will not meet the financial risk criterion.

AAFP Response
The AAFP supports a payment model that includes a primary care global payment for direct patient care, a care management fee, and fee-for-service limited to services not otherwise included in the primary care global fee. Advanced primary care practices with patients that qualify for participation in this payment model would elect one of two levels of primary care global payment. At level one, the primary care global payment for patient care encounters should be a standardized payment that would only include care provided under the E/M and select "G codes" pertaining to ambulatory, office-based, face-to-face care. All other E/M codes

and all non-E/M services, including Healthcare Common Procedure Coding System codes beyond the selected “G codes,” would continue to be billed based on the current fee-for-service payment model. At level two, the primary care global payment should include all E/M codes as well as select “G codes.” All other services would be billed under codes via fee-for-service. Primary care global payments under both level one and level two practices should be risk stratified based on patient complexity and other factors.

(6) Medical Home Expanded Under Section 1115A(c) of the Act
(7) Application of criteria to current and recently announced APMs
In this section, CMS discusses how the Medical Home Model criterion cannot be met unless a Medical Home Model has been expanded under section 1115A(c). To date, there are no Medical Home Models expanded under section 1115A(c). CMS notes that satisfying expansion criteria is not sufficient to meet the requirements of the Advanced APM.

This rule also includes a list of potential Advanced APMs based on a preliminary application of the criteria. There are currently five Advanced APMs expected to be available for the first QP Performance Period, with the Oncology Care Model meeting the criteria beginning in 2018. CMS will post their official determination of Advanced APMs prior to the start of the first QP Performance Period.

AAFP Response
The AAFP believes the definition of a Medical Home Model expanded under 1115A is a very narrow definition that excludes many from participation in the APM program. CMS needs to broaden this definition to encourage participation in alternative payment models and to allow more of these models to meet the qualification criteria. The AAFP believes CMS should particularly modify its criteria regarding reducing spending. The predominant criterion under this requirement should be that a program “does not result in any increase in net program spending under the applicable titles.” As demonstrated by the CPC initiative, a program may take several years before it is able to show a reduction in net spending. Holding a program to such a high standard will significantly delay the expansion of valuable programs. Conversely, a program may be able to demonstrate that it does not result in an increase in net spending much more quickly – allowing for more rapid expansion of programs while also accelerating new demonstrations.

The AAFP appreciates the CPC+ model being made available as an Advanced APM option. CPC+ offers a great opportunity for primary care to enter into an Advanced APM. However, the AAFP is concerned about the limited availability for family physicians to participate in the program due a single enrollment period and limited regions selected. The AAFP strongly urges CMS to institute a rapid review of the original CPC initiative expand the program as quickly as possible.

We believe the Payment Technical Advisory Committee (PTAC) will play a vital role in the development of physician-focused payment models (PFPM) The PTAC will have strong influence on the identification of Advanced APMs, including models that are primary care focused and those that incorporate direct primary care (DPC). We encourage CMS to engage and closely consider the recommendations from the PTAC to ensure there are more primary care Advanced APMs available in the future.

5. Qualifying APM Participant (QP) and Partial QP Determination
In this section, CMS proposes a process for determining which eligible clinicians would be QPs or Partial QPs for a given payment year through their participation in Advanced APMs during a corresponding QP Performance Period. CMS also proposes that after QP and Partial QP threshold calculations have been completed, the agency will use the QP threshold method that is more favorable to the Advanced APM Entity group of eligible clinicians. Furthermore CMS proposes that, beginning with payment year 2021, the agency will conduct the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option.

AAFP Response
For the APM payment year, the AAFP supports a full year (i.e. 12 months) but points out that it not necessarily be a calendar year. The AAFP supports CMS using the QP threshold method that is more favorable to the Advanced APM Entity group of eligible clinicians. The AAFP likewise supports the sequential QP determination starting in 2021.

a. QP Performance Period
CMS proposes that the QP Performance Period is the full calendar year that aligns with the MIPS performance period (for instance, 2017 would be the QP Performance Period for the 2019 payment year).

AAFP Response
As the AAFP called for in a letter sent to CMS before the proposed rule was released, the AAFP urgently and strongly calls on CMS to consider using 2018 as the initial assessment period for MACRA. Perhaps 2017 could be seen and designated as a year for reporting only in preparation for 2018 to be a year of judgement and we would urge this. If this is not possible, we call on CMS to use, at the very least, the second half of 2017 (July 1, 2017 – December 31, 2017) as the initial assessment period for physicians, whether they are participating via the MIPS or APM pathways. Furthermore, the AAFP continues to believe that two-year old data is not clinically actionable or meaningful, and we strongly advise CMS to explore ways to provide realistic and actionable feedback within one year or less. The law mandates that the performance year and payment period be as close together as possible and a two year gap simply ignores this legislative mandate.

b. Group Determination and Lists
(1) Group Determination
For administrative simplicity and other policy reasons, CMS proposes to make the QP determination at a group level.

AAFP Response
Since the AAFP advocates for the PCMH which utilizes a team-based approach to providing care, we support CMS making the QP determination at a group level.

(2) Groups Used for QP Determination
CMS seeks comment on whether to base the QP determination on a to use a Participation List that can be used to identify eligible clinicians or a list of an Affiliated List, which are entities including eligible clinicians who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM, but are not participants and are therefore not on a Participation List.

AAFP Response
Especially in initial years, CMS should allow for maximum flexibility to APMs and we therefore encourage CMS to allow APMs to proactively select which method the APM will utilize. If an APM Entity has both lists, the AAFP would encourage CMS to review and reconcile both list to ensure the broader group of eligible clinicians will be able to receive the APM incentive payment.

(3) Timing of Group Identification for Eligible Clinicians
CMS proposes to identify the eligible clinician group for each Advanced APM Entity at a specified point in time for each QP Performance Period and the agency proposes that this point in time assessment will occur on December 31st of each QP Performance Period.

AAFP Response
We agree that CMS must use a single point in time during the performance period since eligible clinicians within an APM Entity will shift over time. To accommodate partial year performance periods or performance periods that may not be calendar year, we should encourage CMS to change "December 31st" to "the last day."

(3) Exception
CMS seeks comment on the proposal to make most QP determinations at the Advanced APM Entity level and comment on the merits of making all determinations at the individual eligible clinician level versus through some alternative grouping methodology.

AAFP Response
As stated previously, since the AAFP advocates for the PCMH which utilizes a team-based approach to providing care, we support CMS making the QP determination at a group level.

6. Qualifying APM Participant Determination: Medicare Option
(1) Definitions
(2) Attribution
In these sections CMS seeks comment on the proposed methodology for defining the attributed beneficiary population, including comment on alternative methods for capturing the most meaningful cohort of attributed beneficiaries.

CMS also seeks comment on the proposal to use of APM-specific standards as necessary to fulfill our expressed goals for specialty- or disease- focused APMs that may use alternative attribution methodologies.

AAFP Response
In terms of primary care physician attribution, the AAFP strongly recommends the patient be prospectively assigned a primary care physician or provider along with a simple process for the beneficiary to change the physician or provider to whom he or she was attributed.

Regarding the CMS goal for specialty- or disease- focused APMs, the AAFP cautions the agency about needlessly fragmenting care through a plethora of specialty or disease-focused APMs. The AAFP continues to call for APMs to be primary care-centered since there is ample evidence that health systems that are more primary care-oriented are more effective, more efficient, and yield better outcomes than those that are not.

b. Payment Amount Method
(1) Claims Methodology and Adjustments
CMS seeks comment on whether the claims methodology used under the Medicare payment method should align with the proposed claims methodology for purposes of calculating the estimated aggregate payment amount for the APM Incentive Payment.

AAFP Response
The CMS proposal in this regard seems reasonable, and the AAFP supports them.

7. Combination All-Payer and Medicare Payment Threshold Option
a. Overview
Beginning in 2021, in addition to the Medicare Option, eligible clinicians may also become QPs through the All-Payer Combination Option. The All-Payer Combination Option provides an incentive for eligible clinicians to participate in arrangements with non-Medicare payers that have payment designs similar to those in Advanced APMs.

AAFP Response
The AAFP urges CMS to use its leadership role in the Health Care Payment Learning and Action Network (LAN) to drive the convergence of APM frameworks to align incentives, performance measures, and other components of value-based arrangements between public and private payers. According to a 2015 AAFP/Humana study on value-based payments (VBP), six in 10 (61 percent) family physicians' practices submitted claims to seven or more payers during the past 12 months. It is imperative that qualifying physicians are able to execute value-based arrangements, within APM frameworks that are similar in nature and easy-to-understand, and deliver on the promise of population health management. Physicians already face huge administrative burdens with claims adjudication, pre-authorizations, and other tasks that do not contribute to directly improving clinical outcomes—and that is in the current fee-for-service system. It will only get more complicated within APM frameworks. Lastly, family physicians and other primary care providers do not treat Medicare patients or Medicare Advantage patients; they treat and care for patients. Public and private payers need to reduce the administrative burden and needless variability among their APM frameworks so qualifying physicians can concentrate on practicing medicine regardless of payer.

(2) Medicaid APMs
CMS proposes to define a Medicaid APM as a payment arrangement under title XIX that meets the criteria to be an Other Payer Advanced APM as proposed in this section.

AAFP Response
The AAFP supports this definition, as it provides some flexibility for states to implement new payment models and align core requirements for Medicaid APMs with the broader Advanced APM and Other Payer Advanced APM criteria. CMS also intends to generally defer to states in their design of payment arrangements. The AAFP is concerned with ongoing cuts states are making to Medicaid reimbursement rates and believes CMS should formulate additional regulations on preventing damaging reimbursement cuts that lead to diminished access to and quality of care. In addition, CMS should enable states to deem and define their own PCMH program as they are in the best situation to tailor program needs and variable to their markets and populations.

(3) Medicaid Medical Home Models
CMS proposes that a Medicaid Medical Home Model must have the following elements at a minimum:

- Model participants include primary care practices or multispecialty practices that include primary care physician and practitioners and offer primary care services, and
- Empanelment of each patient to a primary care clinician.
- In addition to these elements, CMS proposes that a Medicaid Medical Home Model must have at least four of the following elements:
    - Planned chronic and preventive care.
    - Patient access and continuity.
    - Risk-stratified care management.
    - Coordination of care across the medical neighborhood.
    - Patient and caregiver engagement.
    - Shared decision-making.
    - Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings, population-based payments).

CMS also propose to not mandate a specific method or accreditation process for recognizing Medicaid Medical Home Models.

AAFP Response
The AAFP applauds CMS for developing an appropriate, physician-friendly, and patient-centered framework for Medicaid Medical Homes. The definition incorporates elements from the Joint Principles of the Patient-Centered Medical Home, CPC, and other relevant sources. The AAFP defines an advanced primary care practice, such as a PCMH, as one that is based on the Joint Principles of the Patient-Centered Medical Home and has adopted the five key functions of the Comprehensive Primary Care (CPC) Initiative. These key functions are:

1. Access and Continuity: PCMH practices optimize continuity and timely, 24/7 access to care supported by the medical record. Practices track continuity of care by physician or panel.
2. Planned Care for Chronic Conditions and Preventive Care: PCMH practices proactively assess their patients to determine their needs and provide appropriate and timely chronic and preventive care, including medication management and review. Physicians develop a personalized plan of care for high-risk patients and use team-based approaches to meet patient needs efficiently.
3. Risk-Stratified Care Management: Patients with serious or multiple medical conditions need extra support to ensure they are getting the medical care and/or medications they need. PCMH practices empanel and risk stratify their whole practice population and implement care management for patients with high needs.
4. Patient and Caregiver Engagement: PCMH practices engage patients and their families in decision-making in all aspects of care. Such practices also integrate into their usual care both culturally competent, self-management support and the use of decision aids for preference sensitive conditions.
5. Coordination of Care Across the Medical Neighborhood: Primary care is the first point of contact for many patients and leads in the coordination of care as the center of patients' experiences with health care. PCMH practices work closely with patients' other health care providers to coordinate and manage care transitions, referrals, and information exchange.

The AAFP agrees with CMS not to mandate a specific method or accreditation process for recognizing Medicaid Medical Home Models. We believe this should be the model for all medical home recognized by Medicare and Medicaid under the law. The AAFP remains agnostic on Medical Home recognition programs. We envisioned a recognition process whereby an insurance plan or collection of insurance plans, a quality improvement organization, or a Medicaid program that was offering enhanced payments for PCMH would verify practice capabilities and clinical outcomes. The process of becoming a recognized medical home should be collaborative and focused on the characteristics of the Joint Principles. It should not be a collection of chart extractions, screen captures and checklists. It should be focused on practice and performance improvement.

(4) Use of Certified Electronic Health Record Technology
CMS proposes to require participants to use CEHRT, as defined for MIPS and APMs, to meet the criterion to be an Other Payer Advanced APM.

AAFP Response
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. First, we recommend that the certification process be improved to:

- Increase the testing requirements for interoperability, namely care transitions, secure messaging, and APIs;
- Increase the testing around the support of the common core clinical data set and its integration in the EHR technology; and
- Perform both bench and field testing of CEHRT to sure these capabilities are available in the market place and can be deployed at the practice/hospital site.

Secondly, establish a post market surveillance system to allow reporting by eligible clinicians for events where CEHRT is not living up to the certification requirements. Also allow reporting by patients and clinicians for events where MIPS-eligible clinicians did not have attested functionality available or there was information-blocking behavior. Reporting would help HHS track compliance with attestation and could be a stream of data to pinpoint needed audits.

Thirdly, we recommend that the requirements and scoring of ACI be replaced with the following.

1. Base score requirement would still be 50 percent of the total score for advancing care information
2. To achieve a full base score, the MIPS-eligible clinician must
    a. Use CEHRT and attest that it is in place for the reporting period
    b. An exclusion for times of acceptable down time (system maintenance, switching of systems, de-certification of current system, etc.) would be included as to not penalized eligible clinicians for situations outside of their control
    c. Protect health information as currently proposed in the NPRM
3. Performance score would still be 50 percent of the total score for advancing care information
4. MIPS-eligible clinicians would receive 5 percent points for each of the 10 measure specifications listed in the current NPRM if they attest that functionality was available for use during the reporting period (the same exclusion for acceptable down time would apply here)

While we still disagree that health IT utilization measure are useful in achieving the desired goals, we believe this new proposal complies with current requirements in statue as well as simplifies the ACI component without hindering progress toward the goals of the original meaningful use program and that of MACRA.

In addition to this new ACI construct, we believe that the government needs to ensure the "last mile" of Direct exchange is completed for all those sending and receiving Direct messages and attachments. CMS, as well as the Veterans Administration and the Department of Defense, as federal agencies and a major health care payers, need to ensure that eligible clinicians in the private sector have the capability to easily coordinate care utilizing Direct exchange. To do this we believe that the federal government should (1) ensure the federal government supports the development of national provider directories that include provider Direct addresses, (2) ensure that certification of health IT technology addresses usability and ease-of-use for Direct exchange, and the products are graded with respect to these qualities, and (3) content or payloads delivered as attachments to Direct messages are made more uniform and capable of being computable by senders and receivers using the Direct exchange to share health information.

(5) Application of Quality Measures Comparable to Those under the MIPS Quality Performance Category
CMS proposes that the quality measures on which the Other Payer Advanced APM bases payment must include at least one of the following types of measures provided that they have an evidence-based focus and are reliable and valid:

- Any of the quality measures included on the proposed annual list of MIPS quality measures;
- Quality measures that are endorsed by a consensus-based entity;
- Quality measures developed under section 1848(s) of the Act;
- Quality measures submitted in response to the MIPS Call for Quality Measures; or
- Any other quality measures that CMS determines to have an evidence-based focus and are reliable and valid.

AAFP Response
The AAFP supports reasonable and achievable quality improvement programs that promote continuous quality improvement and measure patient experiences. The AAFP opposes an approach that requires physicians to report on a complex set of measures that do not impact or influence the quality of care provided to patients.

All measures used in MIPS and APMs must be clinically relevant, harmonized among all public and private payers, and minimally burdensome to report. To accomplish this, 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 also supports reducing health disparities as a part of care delivery and urges CMS to move forward with expanding its risk-adjustment methodology in quality measures to incorporate social and economic factors such as race, income, education, and region. Risk-adjusting for socioeconomic status ensures the measures are fair and sets the standard for comparison of physician performance by adjusting for factors outside of the physician's control.

Not adjusting could lead to misleading conclusions about physician performance. As a result, further disparities in care could be magnified.

(6) Financial Risk for Monetary Loss
CMS proposes using criterion that is similar to that proposed for the Advanced APM criterion, with no additional performance criteria.

AAFP Response
The AAFP supports using similar criterion to gauge the payment arrangement structure and not the performance of the participants to determine financial risk for monetary loss. This is precisely what CMS should be doing to align value-based arrangements with private payers to ease administrative burdens on clinicians.

We feel the financial risk criterion developed is overly complex and we urge CMS to simplify it. The AAFP continues to believe family physicians already have risk associated with their own operating expenses. CMS should continue to investigate ways in which to incorporate investment risk into the financial risk for monetary losses standards.

(6)(a)(i) Generally Applicable Other Payer Advanced APM Standard
CMS proposes that the generally applicable financial risk standard for Other Payer Advanced APMs requires a payment arrangement must, if APM Entity actual aggregate expenditures exceed expected aggregate expenditures during a specified performance period:

- withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians; or
- require direct payments by the APM Entity to the payer.

AAFP Response
Similar to our comments on the Medical Home Model, the AAFP adamantly opposes the proposed financial standard for the Other Payer Advanced APM Standard. This financial standard places an arbitrary imposition of financial risk upon clinicians in these models and violates the intent of the law. Therefore, the AAFP strongly believes CMS should remove this financial standard from the proposed rule and that Medical Homes should not be subject to any financial risk.

CMS proposes to remove the provisions of the law that were both placed there to provide a safety net for small and solo practices and designed to help these practices succeed under value-based payment. CMS needs to remove this provision to foster an environment in which a small or solo physician can thrive.

(ii) Medicaid Medical Home Model Financial Risk Standard
CMS proposes that for a Medicaid Medical Home Model to be an Other Payer Advanced APM if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures, the APM must:

- withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- require direct payment by the APM Entity to the payer; or

- require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

AAFP Response
The AAFP strongly believes this provision should be removed from the proposed rule, as the law did not intend for Medical Homes to assume risk of any amount. Medical Homes were intended to be a protected group under the law and the assumption of any risk could pose a threat to their viability.

Similar to the Medical Home Model Standard in the Advanced APM section, the AAFP adamantly opposes this CMS proposed financial standard for the Medicaid Medical Home Model. The AAFP views this as an egregious misinterpretation of the law, which was designed to protect and foster Medical Homes. The financial standard for the Medical Home Model places an arbitrary imposition of financial risk upon clinicians in these models and violates the intent of the law. Therefore, the AAFP strongly believes CMS should remove the Medical Home Model financial standard in its entirety from the proposed rule and Medical Homes should not be subject to any financial risk.

CMS states that they view organizations with more than 50 eligible clinicians as the appropriate threshold because such organizations have demonstrated the capability and interest in taking on higher levels of two-sided risk. The AAFP remains unclear as to how CMS determined 50 ECs was the appropriate number for this threshold. An arbitrary threshold should not be used when determining the amount of financial risk an entity can assume. The assumption of risk should not be determined by a general threshold number of ECs within the organization, it should instead be based on each entity's demonstrated capabilities. Taking on financial risk of any amount is a decision that is not taken lightly by the entities. CMS should afford the entities the same courtesy and develop an appropriate way to determine if an entity is capable of taking on risk. CMS proposes to remove the provisions of the law that were placed there to provide a safety net for small and solo practices and were designed to help these practices succeed under value-based payment. CMS needs to remove this provision to foster an environment in which a small or solo physician can succeed.

We reiterate our steadfast opposition to the Medical Home Model financial risk and the Medical Home Model nominal amount standards. Both provisions need to be removed from the program.

(b) Nominal Amount of Risk
CMS proposes to measure three dimensions of risk to determine whether a model meets the nominal amount standard:

- Marginal risk, a common component of risk arrangements—particularly those that involve shared savings—referring to the percentage of the amount by which actual expenditures exceed expected expenditures that an APM Entity would be liable under an Other Payer APM.
- Minimum loss rate (MLR), a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk.
- Total potential risk, the maximum potential payment for which an APM Entity could be liable under an Other Payer APM.

CMS also proposes a process through which CMS could determine that a risk arrangement with an MLR higher than 4 percent could meet the nominal amount standard, provided that the other

portions of the nominal risk standard are met. In determining whether such an exception would be appropriate, CMS would consider:

- whether the size of the attributed patient population is small;
- whether the relative magnitude of expenditures assessed under the Other Payer APM is particularly small; and
- in the case of test of limited size and scope, whether the difference between actual expenditures and expected expenditures would not be statistically significant even when actual expenditures are 4 percent above expected expenditures.

CMS also proposes that the payment required by the Other Payer APM could be smaller when actual expenditures exceed expected expenditures by enough to trigger a payment greater than or equal to the total risk amount required under the nominal amount standard (as specified in Table 40). This exception ensures that the marginal risk requirement does not effectively require Other Payer APMs to incorporate total risk greater than the amount required by the total risk portion of the standard in order to become Other Payer Advanced APMs.

AAFP Response
The AAFP believes the nominal risk standard as proposed by CMS is complicated and confusing. Eligible clinicians need to be able to understand the amounts of risk they are being asked to assume. Essentially requiring an eligible clinician to become an actuary to understand this regulation is unrealistic. Such a structure will function as a deterrent to eligible clinicians wishing to join an APM entity. There is a vast amount of variability in the risk arrangements this structure could create. A physician who joins an APM with a complex risk arrangement he or she is unable to understand is being set up to fail.

The AAFP encourages CMS to simplify the standard for nominal risk amount to include only the MLR and total potential risk requirements proposed in the regulation. We believe marginal risk introduces an unneeded and unnecessary level of complexity to the nominal risk standard. The total potential risk should be sufficient to meet the nominal risk requirement of the law and is the key measurement of risk. The AAFP believes the MLR is an important component to insure risk is not being triggered by chance. We ask that CMS modify the total potential risk and base it on an entity's Part A and B revenue to provide the assurance that an entity is not assuming more risk than their potential revenues. Entities of all sizes will be able to assume varying levels of risk. It is critical that CMS ensures the potential of these entities to flourish by allowing for risk structures that support success.

(i) Generally Applicable Other Payer Advanced APM Nominal Amount Standard
CMS proposes that for an Other Payer APM to meet the nominal amount standard the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and total potential risk must be at least four percent of the expected expenditures.

CMS also proposes that for Medicaid APMs we propose the same standard as for Other Payer APMs. However, CMS recognizes that Medicaid practitioners may be less able to bear substantial financial risk because they are generally reimbursed at lower payment rates and serve both low-income populations and those with significant health disparities.

AAFP Response
The AAFP believes the nominal risk standard as proposed by CMS is complicated and confusing. Eligible clinicians need to be able to understand the amounts of risk they are being

asked to assume. Essentially requiring an eligible clinician to become an actuary to understand this regulation is unrealistic. Such a structure will function as a deterrent to eligible clinicians wishing to join an APM entity. There is a vast amount of variability in the risk arrangements this structure could create. A physician who joins an APM with a complex risk arrangement he or she is unable to understand is being set up to fail.

The AAFP encourages CMS to simplify the standard for nominal risk amount to include only the MLR and total potential risk requirements proposed in the regulation. We believe marginal risk introduces an unneeded and unnecessary level of complexity to the nominal risk standard. The total potential risk should be sufficient to meet the nominal risk requirement of the law and is the key measurement of risk. The AAFP believes the MLR is an important component to insure risk is not being triggered by chance. We ask that CMS modify the total potential risk and base it on an entity's Part A and B revenue to provide the assurance that an entity is not assuming more risk than their potential revenues. Entities of all sizes will be able to assume varying levels of risk. It is critical that CMS ensures the potential of these entities to flourish by allowing for risk structures that support success.

The AAFP believes underserved populations, such as Medicaid beneficiaries, represent the most vulnerable population in danger of not receiving health care, but also represent the highest potential for improving health care outcomes. Clinicians need the freedom and latitude to explore innovative care delivery, coordination, and management strategies to generate savings and improve care. In addition, mitigating risk for clinicians and their practices to deliver care will enable them to ramp-up in accepting downside risk with rewards to improve outcomes. Lastly, the AAFP is concerned with the ongoing cuts states are making to Medicaid reimbursement rates and believes CMS should formulate additional regulations on preventing damaging reimbursement cuts that lead to diminished access to and quality of care.

(ii) Medicaid Medical Home Model Nominal Amount Standard
CMS also proposes for Medicaid Medical Home Models, the minimum total annual amount that an APM Entity must potentially owe or forego to be considered an Other Payer Advanced APM must be at least:

- 4 percent of the APM Entity's total revenue under the payer in 2019.
- 5 percent of the APM Entity's total revenue under the payer in 2020 and later.

AAFP Response
The AAFP believes strongly that this provision should be removed from the proposed rule, as the law did not intend for Medical Homes to assume risk of any amount. Medical Homes were intended to be a protected group under the law. Furthermore, Medicaid users are more transient than other populations, which adds difficulty in care delivery, management, and coordination.

We reiterate our steadfast opposition to the Medical Home Model financial risk and the Medical Home Model nominal amount standards. Both provisions need to be removed from the program.

(c) Capitation
CMS proposes that full capitation risk arrangements would meet this Other Payer Advanced APM financial risk criterion.

AAFP Response
The AAFP supports a payment model that includes a primary care global payment for direct patient care, a care management fee, and a fee-for-service limited to services not otherwise included in the primary care global fee. Advanced primary care practices with patients that qualify for participation in this payment model would elect one of two levels of primary care global payment. At level one, the primary care global payment for patient care encounters should be a standardized payment that would only include care provided under the E/M and select "G codes" pertaining to ambulatory, office-based, face-to-face care. All other E/M codes and all non-E/M services, including Healthcare Common Procedure Coding System codes beyond the selected "G codes," would continue to be billed based on the current fee-for-service payment model. At level two, the primary care global payment should include all E/M codes as well as select "G codes." All other services would be billed under fee-for-service codes. Primary care global payments under both level-one and level-two practices should be risk-stratified based on patient complexity and other factors.

(7) Medicare Advantage (MA)
CMS proposes that under the All-Payer Combination Option for QP determinations, eligible clinicians and Advanced APM Entities can meet the QP threshold based in part on payment amounts or patient counts associated with Medicare Advantage plans and other payers, provided that such arrangements meet the criteria to be considered Other Payer Advanced APMs.

AAFP Response
The AAFP urges CMS to use its leadership role in the Health Care Payment Learning and Action Network (LAN) to drive alignment of MA APM frameworks with MACRA in order to align incentives, performance measures, and other components of value-based arrangements between public and private payers. Furthermore, we urge CMS to model future advanced APMs after the most successful MA models. It is imperative that qualifying physicians are able to execute value-based arrangements—within APM frameworks that are similar in nature and easy-to-understand—and deliver on the promise of population health management. Physicians already face huge administrative burdens with claims adjudication, pre-authorizations, and other tasks that do not directly contribute to improving clinical outcomes in the current fee-for-service system. It will only get more complicated within APM frameworks. Lastly, family physicians and other primary care providers do not see the people they treat as "Medicare patients" or "Medicare Advantage patients," they are treating and caring for patients. Public and private payers need to reduce the administrative burden and needless variability among their APM frameworks so qualifying physicians can concentrate on their real mission: practicing medicine.

(1) Submission of Information for Other Payer Advanced APM Determination and Threshold Score Calculation
CMS proposes that APM Entities and/or eligible clinicians must submit certain information for CMS to assess whether other payer arrangements meet the Other Payer Advanced APM criteria and to calculate Threshold Scores a QP determination under the All-Payer Combination Option.

AAFP Response
The AAFP adamantly opposes CMS requiring APM Entities and/or eligible clinicians to submit information for CMS to assess whether other payer arrangements meet the Other Payer Advanced APM criteria. The onus of submitting relevant information on payer arrangements should be borne by the payer. Private payers have a better understanding of what information a

public payer, such as CMS, needs in order to consider and determine whether a payer arrangement satisfies the Other Payer Advanced APM criteria. Furthermore, data submission by a smaller number of private payers, rather than a large amount of physicians would ease CMS' burden to assess whether other payer arrangements meet the Other Payer Advanced APM criteria by the nature of lower volume and more congruent data. For example:

- The AAFP has a membership containing over 69,000 active/practicing family physicians, with 61 percent reporting submitting claims to 7-10 payers. Assuming the average number of payers with whom family physicians have relationships with is seven, then CMS will receive 483,000-plus disparate submissions from family physicians. Add to that total the number of submissions from other physicians, specialists, and APM entities, and the danger of CMS receiving duplicative, flawed, and otherwise accurate data is too great for CMS to require submission from APM Entities and/or eligible clinicians.
- The flipside of the calculation reveals a more manageable number for CMS. According to a recent National Association of Insurance Commissioners report card, in 2014, there were 366,089 direct health and medical insurance carriers. That means CMS would be required to process no more than that amount each year when assessing whether other payer arrangements meet the Other Payer Advanced APM criteria.

The burden on private payers to make submissions to CMS on payer arrangements would be minimal. On November 17, 2015 a national payer sent response to CMS' RFI on MACRA, it stated, "As a committed participant in the move to value-based payment, is willing and able to support providers in documenting non-Medicare, APM revenue. In establishing documentation requirements for the all-payer model, we encourage CMS to minimize the administrative burden on providers and on the other entities implementing APMs."
Another national payer's letter from November 17, 2015 expressed a similar statement: "EPs will need to obtain data and information from the private payers to submit qualifying information to CMS. This invariably raises concerns about the administrative burden of providing data and information in general, the risks of revealing proprietary information, and the potential for CMS to audit or judge private payers' APMs."

The AAFP offers an alternative to CMS for receiving data to assess whether other payer arrangements meets the Other Payer Advanced APM criteria—similar to CMS' proposal for Medicaid. In the interest of public and payer alignment and convergence on APM frameworks, payers should be required to submit: (1) the payment amounts and/or number of patients furnished any service through each Advanced APM; (2) the sum of their total payment amounts and/or number of patients furnished any service; and (3) any additional, relevant information the payer believes would help CMS gain a better understanding of the mechanics of APM frameworks. The information should be submitted at least 60 days before the beginning of the QP Performance Period. CMS should, to the extent permitted by federal law, maintain confidentiality of certain information that the Advanced APM Entities and/or eligible clinicians submit regarding Other Payer Advanced APM status in order to avoid dissemination of potentially sensitive contractual information or trade secrets. Other payers are in a better position to deliver the necessary and relevant information to CMS on their own payer arrangements and they would be able to submit "batch" reports on their arrangements, which could include the corresponding clinicians. CMS would then have more accurate and granular data on which clinicians are participating in what payer arrangement with whichever payer, thereby allowing for an increase in program integrity. In addition, it would remove the second-step attestation requirement CMS is proposing for payers to confirm the accuracy of all

submitted information from clinicians. Under the original proposal, payers are the final arbitrator on payer arrangements; this alternative makes them the initial arbitrator. Clinicians should be able to challenge a determination that a payer arrangement in which they are participating does not qualify as an Other Payer Advanced APM and provide additional information for review and revision of the initial determination. This would ensure clinicians are not dependent on a payer to attest the accuracy of submissions, to which they have limited control.

Lastly, the AAFP urges CMS to make this a once-in-a-while process where after a payer submits information on its payer arrangement, CMS would assess whether the payer arrangement meets the Other Payer Advanced APM criteria. If it does, the payer arrangement is certified for a period of time (i.e., three years). The certification would last for a period of time or until the payer makes substantive changes to the arrangement that would disqualify it as an Other Payer Advanced APM. CMS should allow maximum flexibility for private payers to innovate new APM frameworks and not inadvertently create regulations that have a chilling effect on private payers' ability to innovate. The certification process for Other Payer Advanced APMs would add a much-needed regulatory certainty and eliminate much-hated administrative burdens on clinicians. The AAFP believes it would be more manageable for CMS to receive a lower number of submissions from payers than clinicians and to have those submissions contain more accurate and relevant information.

CMS also proposes that for Advanced APM Entities and eligible clinicians participating in Medicaid, CMS will initiate a review and determine in advance of the QP determination period the existence of Medicaid Medical Home Models and Medicaid APMs based on information obtained from state Medicaid agencies and other authorities, such as professional organizations or research entities. The AAFP supports this determination process for the reasons laid out in the preceding paragraph and would urge CMS to apply a similar process for determining whether other payer arrangements meet the Other Payer Advanced APM criteria.

The Balanced Budget Act of 1997 authorized CMS to contract with public or private organizations to offer a variety of health plan options for beneficiaries, including coordinated care plans and preferred provider organizations, private-fee-for-service (PFFS) plans, and other plans. Furthermore the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), updated and improved the choice of plans for beneficiaries under Part C, and changed the way benefits are established and payments are made. As CMS gains continued experience with the Medicare Advantage (MA) program and as new legislation changes MA program requirements, it should periodically revise regulations at Part 422 of Chapter 42 of the Code of Federal Regulations to ensure private payers submit this much-needed information in order to strengthen its ability to select stronger applicants for participation in various programs, remove consistently poor performers, and strengthen beneficiary protections.

(1) Use of Methods
CMS proposes to calculate Threshold Scores for eligible clinicians in an Advanced APM Entity under both the payment amount and patient count methods for each QP Performance Period. CMS also propose that it would assign QP status using the more advantageous of the Advanced APM Entity's two scores.

AAFP Response
We appreciate the agency's intent to align threshold amounts within Medicare and private payers. However, we question the proposed reliance on a combination of billing charges and number of Part B-enrolled Medicare beneficiaries. Under MIPS, eligible clinicians will be

evaluated based on Quality, Resource Use, CPIA, and ACI. The statistical reliability of the measures used in those areas depends on the number of cases in the denominator, which is almost always number of beneficiaries rather than allowed charges. Under the agency's definition, an eligible clinician who provided $11,000 in billing charges to five Part-B enrolled Medicare beneficiaries would not be excluded based on the low-volume threshold. However, neither the AAFP nor CMS should have any confidence in the Quality and Resource Use measures from a five-beneficiary sample. Accordingly, we recommend that CMS define MIPS-eligible clinicians or groups who do not exceed the low-volume threshold as an individual MIPS-eligible clinician or group who, during the performance period, provides care for 125 or more Part B-enrolled Medicare beneficiaries. At the level of 125 or more Part B-enrolled Medicare beneficiaries, both the AAFP and CMS can have confidence in the Quality and Resource Use measures without regard to the billing charges involved.

(ii) Payment Amount Method: Threshold Score Calculation: Numerator
CMS proposes that the numerator would be the aggregate of all payments from all other payers to the Advanced APM Entity's eligible clinicians—or the eligible clinician in the event of an individual eligible clinician assessment—under the terms of all Other Payer Advanced APMs during the QP Performance Period.

AAFP Response
The AAFP support this definition of numerator because if a beneficiary is attributed to an ACO and sees a clinician outside that ACO, payments made to the non-ACO clinician will not count towards this numerator, even if the ACO is an Other Payer Advanced APM.

8. APM Incentive Payment
a. Amount of the APM Incentive Payment
(1) Incentive Payment Base Period
CMS proposes to use the full calendar year prior to the payment year as the incentive payment base period from which to calculate the estimated aggregated payment amounts.

AAFP Response
We support this proposal for the reasons outlined in the proposed rule.

(2) Timeframe of Claims
For the incentive payment base period, CMS proposes to use a complete calendar year of claims with 3 months of claims run-out from the end of the calendar year. CMS estimates that incentive payments could be made approximately 6 months after the end of the incentive payment base period, or roughly mid-way through the payment year. However, CMS proposes that the APM Incentive Payment would be made no later than one year from end of the incentive payment base period. CMS does not propose to set a specific deadline mid-way through the payment year, because it believes doing so could pose operational risks in the event that 6 months is impracticable in a given year for reasons that CMS cannot predict.

AAFP Response
The AAFP supports the proposal to use a full year of claims, plus a 3-month claims run-out in calculating the APM payment incentive. As noted in the proposed rule, on average, 99.3 percent of Medicare claims are processed within three months of the end of the calendar year, which is more than sufficient for calculating the APM payment incentive.

We are very disappointed that CMS did not feel confident enough in its abilities and the abilities of its contractors to commit to actually paying the APM incentive payments before the end of the payment year. We appreciate that unforeseen circumstances can interfere with the best of plans, which is as true for physicians as CMS, a point we hope that CMS will remember in the future. In the meantime, we think it would be reasonable to allow six months for CMS to calculate APM incentive payments and cut checks for the same. Thus, we would urge CMS to commit that APM incentive payments would be made not later than September 30 of the payment year.

(3) Treatment of Payment Adjustments in Calculating the Amount of APM Incentive Payment
CMS proposes to exclude the MIPS, VM, MU and PQRS payment adjustments when calculating the estimated aggregate payment amount for covered professional services upon which to base the APM Incentive Payment amount. CMS does not believe the intent of the APM Incentive Payment is to further magnify existing and future payment adjustments because of overlapping time periods.

AAFP Response
We support this proposal for the reasons outlined in the proposed rule.

(4) Treatment of Payments for Services Paid on a Basis Other Than Fee-For-Service
CMS places payments for services paid on a basis other than FFS into three categories: financial risk payments, supplemental service payments, and cash flow mechanisms. CMS proposes to exclude financial risk payments such as shared savings payments or net reconciliation payments, when calculating the estimated aggregate payment amount.

CMS defines supplemental service payments are Medicare Part B payments for longitudinal management of a beneficiary's health, or for services that are within the scope of medical and other health services under Medicare Part B that are not separately reimbursed through the physician fee schedule. Often these are per-beneficiary per-month (PBPM) payments. CMS proposes to determine on a case-by-case basis whether certain supplemental service payments are in lieu of covered services that are paid under the PFS. In cases where payments are for covered services that are in lieu of services reimbursed under the PFS, those payments would be considered covered professional services and would be included in the APM Incentive Payment amounts. CMS proposes to include a supplemental service payment in calculation of the APM Incentive Payment amount if it meets all of the following four criteria:

- Payment is for services that constitute physician services authorized under section 1832(a) of the Act and defined under section 1861(s) of the Act.
- Payment is made for only Part B services under the first criterion above, that is, payment is not for a mix of Part A and Part B services.
- Payment is directly attributable to services furnished to an individual beneficiary.
- Payment is directly attributable to an eligible clinician.

CMS further proposes to establish a process by which it notifies the public of the supplemental service payments in all APMs and identifies the supplemental service payments that meet its proposed criteria and would be included in the APM Incentive Payment calculations. Similar to its proposal to announce Advanced APM determinations, CMS proposes to post an initial list of supplemental service payments that would be included in its APM Incentive Payment calculations on the CMS website. As new APMs are announced, CMS would include its determination of whether an APM related supplemental service payment would be included in

its APM Incentive Payment calculations, if applicable, in conjunction with the first public notice of the APM. CMS proposes to update the list of supplemental service payments that would be included in its APM Incentive Payment calculations on an ad hoc basis, but no less frequently than on an annual basis.

The care management fee (CMF) paid under CPC+ is an example of a non-FFS payment that would be included in the APM incentive payment calculation. However, the CMF payments for attributed beneficiaries are aggregate payments made to each CPC Practice Site. CMS recognizes that throughout the course of a QP Performance Period more than one NPI may furnish covered professional services to an attributed beneficiary. If that occurs, more than one NPI could potentially receive the corresponding CMF for that eligible beneficiary. CMS does not believe it would be appropriate to count the same CMF for more than one NPI. Therefore, assuming that the CPC+ Model is deemed an Advanced APM and the APM Entity group achieves the QP threshold for a QP Performance Period, CMS could split the CMF amounts equally between the multiple NPIs, or it could develop a method to "assign" the NPI for which the CMFs would be counted in their APM Incentive Payment calculation based on the plurality of visits with that beneficiary. CMS seeks comment on the methods that CMS could use to allocate the supplemental service payments to individual NPIs in these types of scenarios in which payment for a supplemental service payment is made in the aggregate to an APM Entity.

Finally, CMS notes that cash flow mechanisms involve changes in the method of payments for services furnished by providers and suppliers participating in an APM Entity. An example of a cash flow mechanism is the population-based payment (PBP) available in the Pioneer ACO Model and the Next Generation ACO Model. CMS proposes to calculate the estimated aggregate payment amount using the payment amounts that would have occurred for Part B covered professional services if the cash flow mechanism had not been in place. For example, for QPs in an ACO receiving PBP with a 50 percent reduction in fee-for-service payments, CMS would use the amount that would have been paid for Part B covered professional services in the absence of the 50 percent reduction.

AAFP Response
We support CMS's proposal to exclude financial risk payments, such as shared savings or net reconciliation payments, when calculating the estimated aggregate payment amount.

We also support CMS's proposal to include supplemental service payments in the calculation on a case-by-case basis when the four criteria proposed by CMS are met as well as its proposals related to:

- Establishing a process by which it notifies the public of the supplemental service payments in all APMs and identifies the supplemental service payments that meet its proposed criteria and would be included in the APM Incentive Payment calculations.
- Posting an initial list of supplemental service payments that would be included in its APM Incentive Payment calculations on the CMS website.
- Include its determination of whether an APM related supplemental service payment would be included in its APM Incentive Payment calculations, if applicable, in conjunction with the first public notice of the APM, as new APMs are announced.
- Updating the list of supplemental service payments that would be included in its APM Incentive Payment calculations on an ad hoc basis, but no less frequently than on an annual basis.

With respect to allocating the supplemental service payments to individual NPIs in scenarios in which payment for a supplemental service payment is made in the aggregate to an APM Entity, we ideally support the CMF amounts being assigned to the individual NPI to whom the patient is attributed. If that is not possible, then we favor splitting the CMF amounts equally between the multiple NPIs within the APM Entity as long as those NPIs are limited to the ones actually providing care management. We believe that this approach is preferable to developing a method to "assign" the NPI for which the CMFs would be counted in their APM Incentive Payment calculation based on the plurality of visits with that beneficiary. Equally dividing the CMF amounts among the NPIs is the simplest approach, an attractive feature in an otherwise complicated payment system. We also suspect that, in the end, it may also be just as "fair" as the alternative assignment approach.

Finally, concerning cash flow mechanisms, we support CMS's proposal to calculate the estimated aggregate payment amount using the payment amounts that would have occurred for Part B covered professional services if the cash flow mechanism had not been in place. As noted in the proposed rule, to the extent that cash flow mechanisms do not change the overall amount of payments to physicians, CMS's proposed approach makes sense.

(6) Treatment of the APM Incentive Payment in APM Calculations
Section 1833(z)(1)(C) of the Act states that the amount of the APM Incentive Payment shall not be taken into account for purposes of determining actual expenditures under an APM and for purposes of determining or rebasing any benchmarks used under the APM. CMS anticipates that each APM will have in place a procedure to avoid counting APM Incentive Payments toward determining actual expenditures or rebasing any benchmarks under the APM.

AAFP Response
We agree with CMS that it seems reasonable to expect that each APM will have in place a procedure to avoid counting APM Incentive Payments toward determining actual expenditures or rebasing any benchmarks under the APM.

b. Services Furnished Through CAHs, RHCs, and FQHCs
(1) Critical Access Hospitals (CAHs)
In the case of eligible clinicians who furnish services at CAHs that have elected to be paid for outpatient services under Method II, the APM Incentive Payment would be based on the amounts paid for those services attributed to the eligible clinician, as identified using the attending NPI included on a submitted claim, in the same manner as all other covered professional services. CMS proposes that the APM Incentive Payment would be made to the CAH TIN that is affiliated with the Advanced APM Entity, consistent with how CMS proposes to make the APM Incentive Payment to eligible clinicians who practice at locations other than Method II CAHs.

AAFP Response
We strongly disagree with CMS's proposal in this regard. Section 1833(z)(1)(A) of the Act explicitly states, "…there also shall be paid *to such professional* an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part of the preceding year." (Emphasis added) The law clearly requires the APM Incentive Payment to be made to the QP, not the TIN that is affiliated with the Advanced APM Entity through which the eligible clinician met the threshold during the QP performance period.

We agree with CMS that the intent of section 1833(z) of the Act is to incentivize participation in APMs. However, the way to do that, as the law clearly states, is to incentivize QPs, not their affiliated TINs. There is no reward to a QP for participating in an Advanced APM if the QP does not receive the APM Incentive Payment. If a TIN wants to avail itself of a QP's APM Incentive Payment, that is a contractual matter between the TIN and the QP. It is not something for CMS to decide by executive fiat.

Accordingly, we strongly urge CMS to make APM Incentive Payments to QPs (i.e. "to such professional") as identified by either the QP's NPI or TIN/NPI combination. That will incentivize eligible professionals to participate in Advanced APMs. CMS's proposal will not. Further, CMS will not need to worry about scenarios in which an QP changes his affiliation, because the incentive payment will follow the QP regardless, unless the QP has voluntarily surrendered that right by contract with a particular TIN.

(2) Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
Payment for services furnished by eligible clinicians in RHCs and FQHCs is not reimbursed under or based on the Medicare physician fee schedule. Therefore, professional services furnished in those settings would not constitute covered professional services under section 1848(k)(3)(A) of the Act and would not be considered part of the amount upon which the APM Incentive Payment is based. Eligible clinicians that practice in RHCs or FQHCs could still receive an APM incentive payment for covered professional services furnished by those eligible clinicians in other settings.

AAFP Response
We agree with CMS's proposal in this regard.

c. Payment of the APM Incentive Payment
(1) Payment to the QP
CMS proposes that for eligible clinicians that are QPs, CMS would make the APM Incentive Payment to the TIN that is affiliated with the Advanced APM Entity through which the eligible clinician met the threshold during the QP performance period. CMS believes that making the APM Incentive Payments to the TIN associated with the Advanced APM Entity during the QP Performance Period would be most consistent with section 1833(z) of the Act to incentivize participation in Advanced APMs. In scenarios in which an individual eligible clinician may change his or her affiliation between the QP Performance Period and the payment year such that the eligible clinician no longer practices at the TIN affiliated with the Advanced APM Entity, CMS proposes to make the APM Incentive Payment to the TIN provided on the eligible clinician's CMS-588 EFT Application.

AAFP Response
We strongly disagree with CMS's proposal in this regard. Section 1833(z)(1)(A) of the Act explicitly states, "…there also shall be paid *to such professional* an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part of the preceding year." (Emphasis added) The law clearly requires the APM Incentive Payment to be made to the QP, not the TIN that is affiliated with the Advanced APM Entity through which the eligible clinician met the threshold during the QP performance period.

We agree with CMS that the intent of section 1833(z) of the Act is to incentivize participation in APMs. However, the way to do that, as the law clearly states, is to incentive QPs, not their affiliated TINs. There is no reward to a QP for participating in an Advanced APM if the QP does

not receive the APM Incentive Payment. If a TIN wants to avail itself of a QP's APM Incentive Payment, that is a contractual matter between the TIN and the QP. It is not something for CMS to decide by executive fiat.

Accordingly, we strongly urge CMS to make APM Incentive Payments to QPs (i.e. "to such professional") as identified by either the QP's NPI or TIN/NPI combination. That will incentivize eligible professionals to participate in Advanced APMs. CMS's proposal will not. Further, CMS will not need to worry about scenarios in which a QP changes his or her affiliation, because the incentive payment will follow the QP regardless, unless the QP has voluntarily surrendered that right by contract with a particular TIN.

(2) Exceptions
In instances where none of the Advanced APM Entities with which an individual eligible clinician participates meets the QP threshold, CMS proposes to assess the eligible clinician individually, using services furnished through all Advanced APM Entities during the QP Performance Period. When CMS makes the QP determination at the individual eligible clinician level, CMS proposes to split the APM Incentive Payment amount proportionally across all of the QP's TINs associated with Advanced APM Entities.

AAFP Response
Again, the law clearly states that the APM Incentive Payment is to go the professional, not to any of the TINs of associated Advanced APM Entities. Thus, regardless of how CMS determines that an individual eligible clinician is a QP, we believe the APM Incentive Payment should go to the QP.

(3) Notification of APM Incentive Payment Amount
CMS anticipates that the notification of the APM Incentive Payment amount will not occur at the same time as the notification of QP status, but will occur later in the year to allow for accurate calculation and validation of the incentive payment amount. CMS proposes to send notification to both Advanced APM Entities and their individual participating QPs of their APM Incentive Payment amount as soon as CMS has calculated the amount of the APM Incentive Payment and performed all necessary validation of the results.

CMS proposes that the APM Incentive Payment amount notification would be made directly to QPs in combination with a general public notice that such calculations have been completed for the year. For the direct QP notification, CMS intends to include the amount of APM Incentive Payment and the TIN to which the incentive payments will be made. In the case that a QP determination is made at the individual eligible clinician level, and the incentive payment is split across multiple TINS, CMS intends to identify to which TINs it will make the incentive payment, and include the amount of APM Incentive Payment that will be made to each TIN. For the notification to Advanced APM Entities, CMS intends to include the total amount of APM Incentive Payments that will be made to each participating TIN within the Advanced APM Entity, as well as QP specific payment amounts.

CMS seeks comment on other methods for the notification of APM Incentive Payment amount. CMS also seeks comment on the content of such notifications so that they may be as clear and useful as possible.

AAFP Response
We accept that the notification of the APM Incentive Payment amount will not occur at the same time as the notification of QP status, but will occur later in the year to allow for accurate calculation and validation of the incentive payment amount. We therefore agree that notification of QP status should not be withheld from the QP until notice of the APM Incentive Payment amount.

We agree with CMS's proposal to send notification to both Advanced APM Entities (i.e. the TIN) and their individual participating QPs of the APM Incentive Payment amount as soon as CMS has calculated the amount of the APM Incentive Payment and performed all necessary validation of the results. As noted, we believe the law clearly states that the APM Incentive Payment itself should go to the individual participating QP. Consistent with the law, there is no need to tell QPs to which TIN(s) their APM Incentive Payments have been made, since the payment should go to the QP, not the TIN(s).

CMS should notify QPs of their APM Incentive Payment in the same manner that CMS usually notifies such individuals of payments made to them. In addition to the APM Incentive Payment amount, we would encourage CMS to include information clearly describing how the payment incentive was calculated and the amounts used in that calculation, so an individual QP has the information necessary to verify that the payment is correct.

9. Monitoring and Program Integrity
CMS will continue its current vetting and monitoring activities related to APMs as it implements the APM Incentive Payment.

CMS proposes that if an Advanced APM terminates an Advanced APM Entity or eligible clinician during the QP Performance Period for program integrity reasons, or if the Advanced APM Entity or eligible clinician is out of compliance with program requirements, CMS may reduce or deny the APM Incentive Payment to such eligible clinicians. In addition, if the APM Incentive Payment is paid during the QP Performance Period and the Advanced APM Entity or eligible clinician is later terminated due to a program integrity matter arising during the QP Performance Period, CMS may recoup all or a portion of the amount of the payment from the entity to which CMS made the payment.

CMS also proposes that CMS will reopen and recoup any payments that were made in error in accordance with procedures similar to those set forth at §§405.980 and 405.370 et seq. or established under the relevant APM.

CMS proposes that APM Entities and/or eligible clinicians must submit certain information for CMS to assess whether other payer arrangements meet the Other Payer Advanced APM criteria and to calculate the Threshold Score for a QP determination under the All-Payer Combination Option. CMS also proposes that Advanced APM Entities and eligible clinicians must maintain copies of all records related to the All-Payer Combination Option for at least ten years and must provide the government with access to these records for auditing and inspection purposes. If an audit reveals that the information submitted is inaccurate, CMS may recoup the APM Incentive Payment.

AAFP Response
In general, we find CMS's proposal in this regard acceptable and consistent with other CMS program integrity efforts. The one point on which we disagree with CMS is the need for

Advanced APM Entities and eligible clinicians to maintain copies of all records related to the All-Payer Combination Option for at least 10 years. We believe that is an unnecessarily long period to retain such records, and CMS offers no basis for choosing this number. Most states require physicians to retain medical records up to 7 years (or 7 years past the age of majority for pediatric patients). We think 7 years should be equally sufficient for CMS's purposes in this case.

10. Physician-Focused Payment Models
(2) Deadlines for the duties of the Secretary, the PTAC, and CMS
CMS does not propose to set deadlines via regulations for the PTAC's comments and recommendations on proposed PFPMs, the Secretary's response to the PTAC's comments and recommendations, and CMS's testing of PFPMs. CMS believes that setting a deadline for the PTAC's comments and recommendations would interfere with the PTAC's freedom to govern itself and develop its own process and timeline for reviewing proposed PFPMs. CMS's wish to preserve the PTAC's independence and to give it the freedom to determine how and when it would review proposed PFPMs without rulemaking. CMS believes that setting a deadline through rulemaking for the Secretary's review of the PTAC's comments and recommendations, publication of a response to them, and CMS's potential testing of a proposed PFPM submitted to the PTAC is inappropriate because these tasks would take varying amounts of time depending on factors that we cannot predict.

AAFP Response
The AAFP agrees that it is not CMS's place to set a deadline for the PTAC's comments and recommendations, for the reasons given by CMS in the proposed rule. However, we disagree with CMS that it should not set a deadline for Secretarial review of PTAC comments and recommendations and publication of a response to them. Section 1868(c)(2)(D) requires the Secretary to review PTAC comments and recommendations and post a detailed response to the CMS web site. Without even a self-imposed deadline, CMS could effectively avoid this responsibility. We believe that individuals and entities who submit PFPMs to the PTAC using criteria set by CMS should have a reasonable idea when CMS will respond to PTAC comments and recommendations on those PFPMs. As we have noted elsewhere in our response to this proposed rule, we and others understand that things do not always go as planned and sometimes the unpredictable happens. It is a point that we hope CMS remembers when dealing with physicians. In such circumstances, CMS may need to extend its deadline. However, such unusual circumstances should not prevent CMS from establishing a deadline that will work for the typical comment and recommendation from the PTAC.

We agree that CMS need not establish a deadline in regulations for potential testing of a proposed PFPM. However, when CMS posts its response to PTAC comments and recommendations, it should include a general timeline for testing of those PFPMs that it agrees merit testing, so those with an interest in such PFPMs have some idea of what to expect in this regard.

Finally, we stress the importance of advanced APM options being available for physicians to move out of MIPS successfully and quickly as negative payment adjustments increase under MIPS. MACRA clearly intended to move physicians from MIPS to the APM track, and we believe that the PTAC is in a position to assist physician groups, stakeholders, and CMS with this effort. We see PTAC an important part of the process of moving physicians from MIPS into APMs and encourage CMS to be responsive to the committee's recommendations.

b. Definition of PFPM
(1) Proposed definition of PFPM
CMS is proposing to add the following definition of PFPM: An Alternative Payment Model wherein Medicare is a payer, which includes physician group practices (PGPs) or individual physicians as APM Entities and targets the quality and costs of physician services. CMS proposes to require a PFPM to target physician services. Therefore a PFPM must focus on physician services and contain either individual physicians or PGPs as APM Entities, although it may also include facilities or other practitioner types.

CMS proposes to require that PFPMs be designed to be tested as APMs with Medicare as a payer. PFPMs limited to Other Payer APMs would therefore not be PFPMs. CMS does not propose to define PFPM as a payment model that exclusively addresses Medicare FFS payments. A proposed PFPM may also include other payers in addition to Medicare, including Medicaid, Medicare Advantage, CHIP, and private payers. If tested as an APM, a PFPM that includes payers in addition to Medicare would include an Other Payer APM as part of its design in addition to an APM.

AAFP Response
We agree with the proposed definition of a PFPM. As noted in our response to the MACRA RFI last fall, we believe a physician-focused payment model is a mode of compensation in which payment is aimed primarily, if not exclusively, at physicians or physician organizations, rather than other types of health care entities, such as hospitals, post-acute care facilities, etc. Other types of health care entities may be part of physician-focused payment models, but only secondarily or on the periphery. In much the same way that accountable care organizations are often categorized as physician-led or hospital-led, so too with payment models. A physician-focused payment model is physician-led, even if payments made under the model subsequently find their way to hospitals and other health care entities. We believe the proposed CMS definition is consistent with our understanding of the term “physician-focused payment model.”

(2) Relationship between PFPMs and Advanced APMs
CMS does not propose to define PFPMs solely as Advanced APMs. CMS recommends that stakeholders provide information in their proposal about whether their proposed PFPM might be an Advanced APM.

AAFP Response
We agree with CMS’s approach in this regard.

c. Proposed PFPM Criteria
CMS proposes PFPM criteria organized into three categories that are consistent with the Administration’s strategic goals for achieving better care, smarter spending and healthier people: payment incentives; care delivery; and information availability.

Specifically, CMS proposes the following criteria:
- Incentives: Pay for higher-value care.
    - Value over volume: provide incentives to practitioners to deliver high-quality health care.
    - Flexibility: provide the flexibility needed for practitioners to deliver high-quality health care.

    - Quality and Cost: are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.
    - Payment methodology: pays APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.
    - Scope: aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited.
    - Ability to be evaluated: have evaluable goals for quality of care, cost, and any other goals of the Physician-focused Payment Model.
- Care delivery improvements: Promote better care coordination, protect patient safety, and encourage patient engagement.
    - Integration and Care Coordination: encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the Physician-Focused Payment Model.
    - Patient Choice: encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients
    - Patient Safety: aim to maintain or improve standards of patient safety.
- Information Enhancements: Improving the availability of information to guide decision-making.
    - Health Information Technology: encourage use of health information technology to inform care.

AAFP Response
In general, the proposed criteria are a reasonable place to start. However, we were disappointed that they did not include a criterion that, first and foremost, PFPMs should be primary care-centered. There is ample evidence that health systems that are more primary care-oriented are more effective, more efficient, and yield better outcomes than those that are not. We believe that the same is true for PFPMs. Thus, the first criterion should be "How primary care oriented or focused is the proposed PFPM?" That is, to what extent is the proposed PFPM based on first contact, comprehensive, continuous, coordinated, and connected primary care, and to what extent does it encourage treatment on an ambulatory basis rather than in a costly institutional setting? If it is physician-led and primary care-oriented, it should do both of these things. Equally important would be to assess and to what extent does the proposed PFPM use medical homes expanded under section 1115A(c) and to prioritize consideration of such proposals.

Other criteria that we believe the PFPM TAC should use in assessing PFPM proposals include:

- Is the entity to which payment will be directed physician-led? Is a majority of the governing board(s) comprised of independent physicians, members of a participating IPA, or physicians employed by physician organizations, and is a majority of those physicians comprised of family medicine and other primary care representation?

- Where applicable, is patient attribution prospective rather than retrospective? Prospective attribution is preferable, because it allows physicians to know up front for which patients they will be responsible under the payment model. Particularly if CMS expects PFPMs to involve EAPM entities, which, in turn, involves bearing financial risk, the physicians involved need to know for which patients they are at risk.

Among the criteria that CMS does propose to include, we are troubled by the one labeled "Scope" and defined as "aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited." We disagreed with a similar criterion in the RFI.

First, we believe that the opportunity for physicians to participate in proposed PFPMs should not be limited by the fact that they may have had the opportunity to participate in another PFPM with CMS. Prior opportunity does not equate to prior participation, and prior participation should not restrict a physician from future participation in innovative payment models.

Another reason we disagree with this particular proposed criterion is that it seems intent on fostering a plethora of specialty-specific PFPMs, and we believe CMS should focus on primary care PFPMs. We do not need to replace the current fee-for-service system, and its multiplicity of subspecialists driving volume rather than value, with APMs driven by a multiplicity of sub-specialist PFPMs.

Elsewhere in the proposed rule, CMS states that it believes concurrently implementing multiple PFPMs that attempt to solve the same clinical or payment issue may not be the most efficient use of limited resources, and may complicate the evaluations of some or all of the relevant models. Such thinking seems designed to preclude innovation in the form of alternative or new ways of addressing existing problems. Innovation is not, and should not be, limited to uncharted territories. In medicine, there is often more than one way to address a problem, and the preferred solution may vary depending on the circumstances. Further, new solutions may prove preferable to old ways of doing things. For example, the treatment of polio gave way to prevention with the introduction of the polio vaccine.

We strongly urge CMS to either not include this criterion or, failing that, modify it, so it is more in line with Innovation Center criterion No. 5, which states, "Demographic, clinical and geographic diversity – Does the model target key diverse patient and practitioner populations that CMS has yet to engage in other models, or geographic regions with previously low participation in CMS models?"

d. Facilitating CMS Consideration of Models Recommended by the PTAC
To facilitate and potentially expedite the consideration of models for testing following PTAC review and recommendation, CMS suggests "supplemental information elements" stakeholders may include in their PFPM proposals to assist in CMS's review. CMS does not propose to require these elements as PFPM criteria and defers to the PTAC on how it may approach requesting any supplemental information beyond that required to meet the PFPM criteria.

(3) Supplemental Information Elements Considered Essential to CMS Consideration of New Models
There are three pieces of information CMS considers fundamental to evaluating new models:

- A description of the anticipated size and scope of the model in terms of eligible clinicians, beneficiaries, and services.
- A description of the burden of disease, illness or disability on the target patient population.
- An assessment of the financial opportunity for APM Entities, including a business case for how their participation in the model could be more beneficial to them than participation in traditional fee-for-service Medicare

In addition, CMS recommends that proposed PFPMs submitted to the PTAC include information about whether the stakeholder or individual submitting the proposal believes it would meet the criteria to be an Advanced APM.

AAFP Response
We believe that this is a reasonable list of additional pieces of information for which to ask and much shorter than the list that CMS included in its RFI. To the extent that we questioned many of the elements listed in the RFI, we support this succinct list of essential elements.

e. MIPS and APMs RFI Comments on PFPM Criteria
CMS responds to some of the comments on PFPM criteria that it received in response to the RFI last fall. Of note, CMS does not believe it should limit proposed PFPMs by adding specialty-specific criteria.

AAFP Response
We agree that CMS should not limit proposed PFPMs by adding specialty-specific criteria. We urged CMS to use a single set of criteria in our response to the RFI. We appreciate that they are proposing to go in this direction.

III. Collection of Information Requirements
A. Wage Estimates
To derive wage estimates, CMS used data from the U.S. Bureau of Labor Statistics' (BLS) May 2014 National Occupational Employment and Wage Estimates and the December 2015 Employer Costs for Employee Compensation.

AAFP Response
The AAFP concurs with the chosen wage estimate for physicians and urges CMS to update it to the 2015 figure that is available plus an adjustment to account for inflation. We concur with the assumption of a 100 percent figure for fringe plus overhead and acknowledge that using BLS for wage estimates is appropriate and that we do not have other or better sources of data to offer.

B. A framework for Understanding the Burden of MIPS Data Submission
Eligible clinicians that are not in APMs will submit data either as individuals or groups to the quality, ACI and CPIA performance categories. For APMs, the entities submitting data on behalf of the model participants will vary across categories of data and APM model. As it is proposed, the SSP APM will submit ACI and CPIA performance category data on behalf of their participants. In other APMs, eligible clinicians will submit data as individuals to ACI and CPIA. For Advanced APMs, Partial QP elections will be submitted by the Advanced APM Entity on behalf of the participating eligible clinicians.

C. ICRs Regarding Quality Performance Reporting Category and Previously Approved Under PQRS

CMS discusses the information requirements for eligible clinicians who are not APM participants. They estimate that 703,467 MIPS-eligible clinicians will submit quality data to the quality performance category. They assume those that submit through claims, QCDR, EHR, and CMS Web Interface for PQRS will continue to do so for MIPS. For MIPS-eligible clinicians or groups, the burden associated with the requirements of the MIPS quality performance category is the time and effort associated with MIPS-eligible clinicians identifying applicable quality measures, collecting the necessary information, and reporting the information. This will vary between practices. They estimate a total of 6 hours as the amount of time needed for a MIPS-eligible clinician's billing clerk to review the measures list, review the submission options, select the most appropriate submission option, identify the measures they can report on, review the measures, and incorporate the submission of selected measures into the workflow. (6 hours x $34.20=$205.20.) They also estimate it will take 1 hour of physician time to review this process. (1 hour x $182.46= $182.46).

AAFP Response

Though CMS does not request comments on this section, the AAFP is compelled to remind CMS that not all physician practices, specifically small practices, have a "billing clerk." The work described most often falls to a physician. Therefore, the AAFP disagrees with the projected financial assumptions. In these practices, the activities assigned to the "billing clerk" will fall to the physician, which changes the assumption to have a higher-cost impact. Also, physicians will likely need more than one hour to review the measures in order to understand their specification, evaluate their current practice as it applies to the measure, and plan anticipated changes in practice. In addition, what is not figured into these projections is the "ramp up" of education needed for office staff and clinicians to understand this overly complex program. Also omitted from consideration of burden was the building of specifications into the EHR system to capture the measure numerator and denominators. This could take hours for each measure and could require, for most, the hiring of an outside consultant. At minimum, it would require negotiation with the EHR vendor. The AAFP reiterates that small practices function differently than larger health systems. The functions carried out by ancillary staff in a health system are often handled solely by a physician in a small practice. Thus, for small practices with a lean staff, the estimates made here are very low and most be reconsidered.

We appreciate the opportunity to comment on this proposed rule and make ourselves available for any questions you might have. Please contact Shawn Martin, Senior Vice President for Advocacy, Practice Advancement and Policy at smartin@aafp.org or 888-794-7481 ext. 2500.

Sincerely,

Robert L. Wergin, MD, FAAFP
Board Chair