AMERICAN
COLLEGE *of*
CARDIOLOGY

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.ACC.org

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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.

December 19, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: 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 [CMS-5517-FC]

Dear Acting Administrator Slavitt:

The American College of Cardiology (ACC) appreciates the opportunity to comment on 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** final rule as published in the Federal Register on November 4, 2016.

The ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. The ACC also produces the *Journal of the American College of Cardiology*, ranked number one among cardiovascular journals worldwide for its scientific impact.

The ACC is pleased with the depth of changes that the Centers for Medicare and Medicaid Services (CMS) made in the final rule based on the nearly 4,000 comments received from the public. However, even with the changes made in the final rule, CMS still has a heavy lift ahead in ensuring that the QPP is implemented in a way that truly supports improved patient outcomes without distracting clinicians from their priority of treating patients. The comments in this letter address the following areas where CMS should make further improvements to the QPP in order to achieve this goal.

- The QPP transition period must extend beyond the 2017 performance/2019 payment year.

- While virtual groups are a concept that can help small practices succeed under MIPS, CMS must carefully test this reporting option and ensure that the infrastructure can support data collection and reporting.

- While CMS made many improvements to the MIPS policies in the final rule, CMS should continue to develop this pathway so that it truly is one seamless reporting program rather than the separate, disjointed legacy programs of Physician Quality Reporting System (PQRS), the EHR Incentive, and the Value-Based Payment Modifier.

- CMS should continue to update the list of Advanced Alternative Payment Models (Advanced APMs) and refine policies to make this QPP participation pathway available to more specialists and clinicians.

- While the final rule includes substantial detail on the 2017 QPP policies, there are still areas that need to be clarified in order for clinicians and groups to translate these policies and implement them into practice. CMS must continue to release additional guidance and education as efficiently as possible.

Transition Period

The ACC recommends that CMS view both the 2017 performance period/2019 payment period and the 2018 performance period/2020 payment period as transition years. Recognizing the 2017 performance year as a transition year from the existing programs to the QPP will greatly assist the clinicians impacted by this change. Yet, under the current timeline, clinicians and groups will receive feedback on their 2017 performance in 2018. Until that feedback is received and understood by clinicians, any discussions regarding the impact of MIPS implementation on clinician performance and payment is speculative. The College is concerned that if clinicians and groups receive their first feedback reports in the fall of 2018, similar to the current program timelines, this will not provide clinicians, specialty societies, and CMS any time to assess the first year of the program and to recommend improvements to the QPP during the rulemaking period for CY 2018. Furthermore, this may not allow sufficient time for clinicians and groups to fully understand their feedback and, if necessary, file a review of their payment determination with CMS.

The College is concerned that the timeframe between the availability of performance feedback the start of the 2018 performance year on January 1 provides too narrow of a window for clinicians and groups to understand what changes need to be made in order to improve their performance or advance to a longer reporting period in 2018. **For this reason, the College requests that CMS maintains consistency between the reporting requirements and thresholds for 2017 and those that will be proposed for 2018. The College also recommends that CMS preserve the "Pick Your Pace" reporting options for 2018 and continue to implement additional solutions that support clinicians and groups in the transition to the QPP.**

CMS should take the opportunity to use the time following this interim final rule comment period to continue open and meaningful discussions with practicing clinicians, specialty societies, and the public. As discussed in this comment letter, there are still many aspects of the QPP that can be improved, but will require collaboration on technical conversations beyond what is possible through the rulemaking process. The ACC has greatly appreciated the level of collaboration that CMS staff and leadership have demonstrated to date and looks forward to continued work and discussion throughout the transition period.

Virtual Groups

The ACC supports CMS' decision to delay implementation of virtual groups until an infrastructure for this form of reporting can be developed. The College recognizes however, that there is an urgency to implement virtual groups as another mechanism to support small and rural practice performance in MIPS. CMS intends to implement virtual groups for the 2018 performance period. CMS must also provide implementation support to those clinicians participating in virtual groups, as this will require updating systems to capture a new group identifier and familiarity with new submission processes and methodologies for MIPS reporting. Clinicians and practices using this option will likely be those small and rural clinicians and practices that cannot afford to invest time and resources into a new reporting option if it does not result in improvements to their MIPS performance. Virtual groups should not be penalized if it is determined that there are issues with the structure or methodology of this reporting option that is not the fault of the group. **If CMS meets its goal of implementing virtual groups in 2018, then the College recommends that CMS allow practices to test the virtual group year in their initial year of performance, similar to the Pick Your Pace program created for 2017 and that should be extended to the 2018 performance period.**

CEHRT and Virtual Groups

While virtual groups can provide an opportunity for clinicians in small practices to share the same information and resources that larger practices can dedicate to improve patient care, it may be difficult to implement virtual groups without more information on overall program performance for the transitional year. Factors that those interested in virtual groups should consider in order for their CEHRT to have interoperability with other CEHRT are: potential variation in collecting and reporting on similar quality measures; inconsistencies in the capabilities of CEHRT used in different practices; and differences in workflow utilizing CEHRT between clinicians. Performance on quality measures is a concern, as inconsistencies in the ability of CEHRT to collect and report quality data can result in variation in performance between clinicians where none exists. The use of a variety of types and editions of CEHRT implemented at different practice sites can result in not all members using CEHRT with the same capabilities or in the same way, potentially resulting in scoring variations between members. Differences in workflow and other processes of patient care between members could drop the average score for those utilizing shared reporting as well.

Members of a virtual group using a single form of CEHRT will have some advantages over members utilizing a variety of CEHRT technology to meet reporting requirements for virtual groups but only if each installation of CEHRT is equipped with the same options and configured similarly. In reality, most implementers of CEHRT incorporate some customization in individual installations, and there is a distinct possibility that these differences in capabilities could introduce variables in datasets that prevent accurate comparison of performance and result in low scores for the participants even if they are using the same form of CEHRT. Evaluation of the capabilities of any form of CEHRT for all members to collect and report on program requirements is critical. Even if CEHRT is identical within the group, a thorough understanding of variation in practice between members is needed, as well as any impact these differences might have on reporting. With this information, clinicians can determine if their particular implementation of CEHRT can meet the requirements of participation in virtual groups or if modifications to CEHRT are needed for effective participation. **The College recommends that CMS work with vendors and practicing clinicians to develop tools and guidance for those interested in participating in virtual groups to help them evaluate both CEHRT and practice variations and ensure program success.**

It is difficult to identify the exact timeframe needed for virtual groups to build a system or coordinate infrastructure to collect measure data. A collective understanding of the meaning and interpretation of data is critical; otherwise, members of virtual groups will not have the tools to use that data to improve patient care. The ACC cautions that lack of clear benefit to patients and complications in implementation may present a significant deterrent to practices that could most benefit from forming virtual groups. **The College recommends that CMS proceed carefully in implementing virtual groups after thorough evaluation of program performance in the transitional years and test the virtual group model thoroughly before establishing program requirements.**

Merit-Based Incentive Payment System (MIPS)

Quality

At 60 percent of the MIPS composite score for the 2017 performance period/2019 payment period, CMS should provide ongoing support to clinicians and groups during this transition year to ensure that participants are successful under this category.

Data Completeness Thresholds

The College thanks CMS for reducing the data completeness thresholds under the proposed rule to 50 percent of the eligible patient population for a measure. As proposed, requiring clinicians and groups to report on at least 90 percent of their eligible patient population would have been overly burdensome and a barrier to clinicians and groups successfully reporting MIPS measures.

CMS anticipates a gradual increase in the threshold starting with an increase to 60% of eligible patients in 2018 and higher thresholds in later years. The College is concerned that further increases of the threshold will limit successful performance. For example, there may be some clinicians and groups that switch to EHR systems during the calendar year that are not interoperable with the QCDR. Because of the change, they may not have complete data on all of their patients when submitting measure data for reporting.

The ACC appreciates the gradual approach, but also recommends that CMS only increase thresholds to the point where data completeness needs and the administrative impact on participating clinicians and groups is balanced. CMS should not propose unreasonably high thresholds without strong rationale for doing so.

Global and Population-Based Measures

The ACC continues to recommend elimination of the claims-based global and population-based measures derived from the Value Modifier as part of the MIPS quality score. CMS stated in the proposed rule that there have been historical issues with the statistical reliability of these measures when applied to small practices and solo practitioners, and also states that clinical risk adjustment improvements still need to be implemented into these measures. In addition, these measures for acute and chronic conditions and hospital readmissions may unintentionally score clinicians on events outside of the direct care provided to a patient. Until better measures can be developed, CMS should promote care coordination and population-level care through additional credit for clinical practice improvement activities and quality measures focused on population-based care.

The ACC is also concerned with the lack of transparency on these measures for the 2017 performance year. To date, most of CMS' resources have addressed the requirement for most clinicians to report at least 6 quality measures or 1 specialty measure set, including one outcome measure, but there has been

little mention of the population-based measures. **While the College recognizes that these measures are claims-based and require no separate reporting by clinicians or groups, CMS should communicate and educate on these measures now to eliminate any surprise once clinicians and groups receive their initial MIPS performance feedback should the Agency decide not to eliminate these measures.**

Cross-Cutting Measures

The ACC supports CMS' decision not to finalize the requirement that clinicians and groups report one cross-cutting measure. The College encourages CMS to adopt this policy in future years of the MIPS. While having a common set of measures available to clinicians regardless of specialty or practice type is an aspirational goal, the College believes that requiring a cross-cutting measure may require clinicians to report certain measures just to meet this requirement, not because the particular measure is clinically relevant to the care they provide.

High Priority Measures

CMS should recognize non-MIPS measures as high priority measures if they are considered outcome, appropriate use, patient safety, efficiency, patient experience, or care coordination measures. Clinicians reporting these types of measures through a qualified clinical data registry (QCDR) should be eligible for the same bonus points that apply to MIPS measures listed in the final rule.

Measures for Non-Patient Facing Clinicians

CMS acknowledges that certain specialties and non-patient facing clinicians may not have a comprehensive list of quality measures to select from based on the nature of their practice. As MIPS is implemented and data is collected, CMS should ensure that these clinicians are not being unfairly penalized. The ACC previously recommended solutions such as increasing the Clinical Practice Improvement Activity weight for these clinicians and providing them with credit for activities such as participation in laboratory accreditation and safety standards. While this recommendation was not adopted for the 2017 performance year, the ACC encourages CMS to continue to explore ideas on how to more accurately recognize the performance of clinicians in the non-patient facing category.

Advancing Care Information

Barriers to Achieving Program Success

As CMS is aware, the ACC has long expressed support for an incentive program that rewards clinicians for adoption and use of health IT to improve patient care. The College applauds CMS' response to comments on the proposed rule by establishing a more flexible scoring methodology, eliminating unnecessary measures and objectives, emphasizing measures relevant to practice, and increasing options for clinicians to earn bonus points. These modifications in the final rule demonstrate the Agency's desire to develop a program accessible to more clinicians. **However, the ACC has some concerns regarding clinician's ability to complete some measures and objectives due to factors beyond their control. These factors include lack of interoperability between systems, occurrences of data blocking, and the growing threats to healthcare information security.**

Interoperability

Information interoperability between CEHRT is critical to complete base and performance measures in the health information exchange objective. Currently, few clinicians are successful at exchanging clinical information, such as discharge summaries, progress notes, and referrals, between different forms of

CEHRT. Problems in exchanging clinical information between diverse CEHRT begin with difficulties in identifying the correct patient in large databases that contain many patients with similar names and birthdates. Clinical information in the summary of care may be out of order or contextually incorrect when shared between different EHRs. Clinicians attempting to exchange clinical information sometimes resort to work-arounds such as printing clinical documents from the EHR, and faxing these documents to the receiving clinician. While clinicians can meet the requirements to complete measures in the health information exchange objective with work-arounds, they are not using the capabilities of CEHRT as intended and will not be able to until issues of interoperability are addressed. **The College recommends that the ONC establish more stringent testing and verification of interoperability as part of the both the certification and surveillance programs.**

Information Blocking

The easy flow of patient health data between diverse CEHRT and tools that interface with CEHRT is not only essential to completing the objectives and measures of health information exchange and public health and clinical data reporting, it is critical to the provision of safe and effective patient care. Information blocking is seldom caused by clinicians, but rather, health IT vendors and developers. The College has experienced information blocking resulting in the restriction information exchange between diverse CEHRT through several means including unnecessary technical barriers, contract stipulation preventing information exchange, and exorbitant fees to enable the capability. Clinicians have little recourse when suspected information blocking has occurred other than to complain to ONC. **The ACC urges the ONC to investigate cases of suspected information blocking and use the leverage of removing certification from products by vendors and health IT developers that are engaging in information blocking.**

Health Information Security

Instances where the security of individuals' electronically protected health information has been compromised are on the rise. Large data breaches in 2015 resulted in over 112 million patient records being lost, stolen or inappropriately disclosed. The College appreciates CMS' acknowledgement of this growing concern by requiring clinicians to take an active role in protecting patient health information. Yet, the ACC is concerned that the increasing sophistication of these attacks on the security of health care information requires a more unified response from the ONC, especially in cases where vulnerabilities in information security can be clearly attributed to health IT vendors and developers of CEHRT. **The ACC recommends that the ONC take a more active role in the evaluation and resolution of security vulnerabilities, including**:

- **Improved testing for security risks in the certification process**
- **Actively investigate cases where the security of patient data has been compromised in CEHRT to determine the cause**
- **Respond quickly to cases where security breaches can be clearly attributed to health IT vendors and developers of CEHRT by engaging the appropriate authorities, and if needed, removing certification altogether**
- **Provision of in-depth educational resources for clinicians around prevention of security breaches and updating of these resources when new threats are verified, as well as when investigations identify common clinician behaviors that can affect data security**

Improvement Activities

The College supports the reduction in required Improvement Activities (IAs) as well as the flexibility granted to small practices and MIPS APM participants. The reduced requirement thresholds in addition to the broad list of 93 activities recognized for credit ensures that clinicians and groups will be able to find ways to meet this new category. As CMS looks to improve the IA category in future years, the Agency must preserve intent of this category to reward clinicians and groups for activities that contribute to improved patient outcomes. The most impactful IAs to a clinician or group may vary based on practice type, specialty focus, and patient demographic. CMS should not mandate that clinicians or groups participate in any specific activity or domain in order to receive credit for this category.

The ACC also supports attestation as a reporting mechanism for the IA category and encourages CMS to maintain this option in future years of the program. Not all IAs are designed to be reported through an EHR system, qualified registry, QCDR, or claims. The attestation mechanism will ensure that no clinician is barred from reporting participation in a particular activity just because his or her systems do not have the appropriate infrastructure for reporting.

In order for clinicians and groups to successfully meet the requirements of the IA category of MIPS, additional guidance is needed as soon as possible. The final rule includes little detail on the reporting process for IAs. The College believes that guidance addressing the following questions will help clinicians and groups understand what they need to do:

- How will clinicians, groups, and reporting mechanisms be required to report IAs? Will these need to be documented based on the codes provided in the final rule for each activity?
- Should clinicians and groups anticipate potential audits of attested IAs? If so, what records should they maintain for CMS?
- How will clinicians and groups know which IA to report? It is clear that some IAs are tied to a specific initiative (e.g., Participation in CMMI models such as the Million Hearts Campaign); however, other IAs are more general (e.g., care transition documentation practice improvements). For those activities not tied to a specific initiative, how will clinicians and groups identify the appropriate IA? Is there any impact to the clinician or group selecting the "wrong" IA?
- Will the process for future IAs require a certain threshold of evidence demonstrating that an activity contributes to quality improvement? What requirements will apply to any new IAs?
- Does CMS intend to remove IAs from future versions of this list? If so, what will be the criteria for removing an IA? If an IA is removed, will clinicians and groups reporting that activity be permitted to continue reporting that activity for an additional "grandfathered" year, or will they have to find new IAs for the next performance year?

Providing guidance to the above questions will not only assist clinicians and groups, but also the reporting mechanism vendors and program sponsors that will help participants report this category.

Cost

The ACC strongly supports CMS' decision to reduce the Cost category to zero percent of the MIPS score in 2017. CMS intends to meet the statutory requirement of weighting the Cost category at 30 percent of the MIPS score by the 2021 payment year and beyond. As CMS phases this category into the program, the ACC emphasizes the need to improve the measures and attribution methodology used under this category to ensure that Cost is measured accurately based on real-world clinical care and patient scenarios.

Claims-Based Measures for the Cost Category

The ACC continues to oppose the use of the total per capita cost measure for all attributed Medicare beneficiaries and the Medicare Spend Per Beneficiary (MSPB) measure and recommends that these not be used to measure MIPS Cost performance. These measures are designed to measure cost at the hospital-level, not the clinician-level. This places clinicians at a disadvantage as they are held responsible for the beneficiary's total cost of care arising out of a hospitalization. Many Medicare beneficiaries who are hospitalized will be admitted with multiple conditions, each treated by a different clinician or team. For example, a beneficiary admitted after suffering an acute myocardial infarction (AMI) may likely also suffer from diabetes and may also be treated for diabetic ulcers or other conditions after admission. While the cardiologist may manage the beneficiary's AMI diagnosis, other members of the care team may treat the diabetes symptoms, such as debridement and treatment of the wound. It would be unfair to attribute the total cost of care for the entire hospitalization to the cardiologist as he or she is not responsible for the services related to the diabetes care. Moreover, clinician services make up a fraction of the total cost of care provided to hospitalized beneficiaries. **Clinicians should not be held accountable for costs upon which they have little control.**

Episode-Based Measures for the Cost Category

As stated in comments to the proposed rule, the ACC supports the use of episode based groups for resource use measurement as long as these groups are evidence-based, validated, and reflect real-world patient scenarios from the clinician perspective. The ACC recognizes that the MACRA statute provides CMS with a swift timeline for developing and implementing new episode groups for cost measurement. While the College appreciates the ongoing public comment process and clinical expert workgroup convened by CMS' contractor as part of this effort, the College is concerned that the current process is being conducted in a manner that is not collecting meaningful input from the clinician community. The College is working with several clinicians participating in the clinical expert workgroup convened by CMS' contractor. These clinicians were not provided with enough time to review and understand the episodes in enough detail to provide substantive feedback on how the episodes should be modified. It also remains unclear how much the input provided through this workgroup will contribute to later versions of the episodes. CMS must work with its contractor to improve the transparency of current episode group development efforts so that any clinical flaws with the episodes can be addressed prior to any larger pilot or implementation.

As CMS develops new episodes, the College encourages the Agency to identify the quality metrics that would align with each episode of care. Value-based care can only be achieved if quality is maintained or improved while cost is lowered. One risk of an episode-based approach to measuring cost is that clinicians may be penalized for higher spending even if that spending results in improved quality outcomes. This scenario is particularly relevant to the care of patients with chronic conditions who may require services beyond what is included in the average episode. CMS should identify episodes with corresponding quality measures to avoid incentivizing clinicians for under-treating patients. **The College is concerned that if this is not done early in the process, the poor patient outcomes resulting from under-treatment in one year will eventually manifest as more complex conditions subsequent years.**

Any episode used to calculate the MIPS score must first go through a pilot period of at least one performance year. The ACC supports the approach by CMS to provide clinicians with their Cost performance on an informational basis only for the 2017 performance year and recommends that CMS continue this approach in future years of the program to introduce new episodes. This pilot period will allow clinicians to become familiar with their Cost performance in new episodes and have a benchmark for performance before the episodes are used for performance calculations and payment adjustments. This pilot should also include use of the patient encounter codes currently under development. The pilot period

will also allow time for CMS, its contractors, specialty societies, and clinicians to identify any issues with the design of the episodes, the attribution methodology, or potential barriers in systems collecting the data needed to calculate these episodes before the episodes factor into MIPS performance scores.

Group Reporting

The ACC supports the continuation of individual and group level reporting options under MIPS; however, CMS should continue to explore reporting options and scoring methodologies where the contributions of specialists can be better reflected in the overall group score. The College continues to be concerned that under the group reporting structure, clinicians, particularly those in large multi-specialty groups, may be scored on the performance of others in their group if the group does not select metrics applicable to their practice. While an ideal group level reporting structure would encourage coordination, teamwork, and shared responsibility, it can only do so if every clinician can trace their performance back to the overall performance of the group. The College recognizes that remedying this issue may require actions outside of CMS' control, such as specialists advocating to their administration to include specialty-specific metrics in their Quality and IA reporting, or decisions to break multi-specialty practices into different Taxpayer Identification Numbers (TINs).

CMS will still track all clinicians at the TIN/NPI level despite their level of reporting for purposes of applying the payment adjustment to Medicare Part B claims based on the individual services provided by individual clinicians. If CMS is tracking clinicians at both the individual and group levels, there should be some way to reconcile group and individual performance.

Scoring

The flexibility finalized for the initial year of the MIPS program has resulted in a range of scoring weights and methodologies depending on factors such as a clinician's or group's practice size or participation in a MIPS APM. The ACC acknowledges CMS' position that under MIPS, if clinicians are doing what they should be doing to improve value-based care to beneficiaries, then there should be no need for them to think about the scoring methodologies in MIPS in detail on a daily basis. While the College agrees that this should be the outcome of an effective MIPS program, clinicians and groups still need to know how they are being assessed. The College has worked with practices who have received their feedback reports under the current PQRS and Value-Based Payment Modifier programs. Current information on scoring methodologies for these programs is fragmented and difficult for the average clinician or administrator to understand. As a result, clinicians reading their feedback reports are still unclear as to why they may have received a certain penalty, score, or lack thereof. **CMS must provide resources that clearly walk clinicians through the scoring methodologies used under MIPS. These resources must also accompany actionable feedback reports that are meaningful to clinicians and administrators. These resources should include guides on how scores are calculated, how benchmarks will be set, and how to interpret scoring data.**

Benchmarking Performance

While the College enthusiastically supports the flexible reporting requirements in the final rule, the ACC does have some concerns that establishing standards for benchmarking based on data from the transition year of the program may not accurately reflect program performance. Factors that could affect the quality and accuracy of data from the transition year of the program include variation in the data collected, reported and shared between and by CEHRT, variances in quality reporting, and variation in the effective use of CEHRT.

Variation in the data collected by CEHRT is due in part to the disparity in capabilities between CEHRT certified to the 2014 edition and CEHRT certified to the 2015 edition, as well as issues of interoperability that affect information exchange. The disparity in capabilities between editions requires that clinicians report on different ACI measure sets as the different editions of CEHRT do not support the same level of data capture. Concerns around interoperability affect clinicians' ability to share and exchange patient data or share data between EHRs and tools such as disease registries.

Variations in quality reporting can be attributed to the lack of clear definitions of clinical terminology described in quality measures, which can cause confusion for implementers of quality measures and result in inaccuracies in clinician performance. New program participants may not have the same level of familiarity with workflows that utilize CEHRT for meaningful use as participants with previous experience with the EHR Incentive program, affecting overall program performance. The ACC remains hopeful that these concerns will not persist into future program years. All clinicians will transition to 2015 edition CEHRT in 2018, and data capture capabilities between editions will be eliminated. A number of federal and independent initiatives are actively working to resolve issues of CEHRT interoperability and facilitate information exchange. In 2016 CMS initiated a program to improve quality measures, simplify the implementation and increase the accuracy of quality reporting. Lastly, all clinicians participating in the QPP will have greater experience using CEHRT effectively in patient care, and overall program performance should reflect this.

The College recommends that CMS exercise caution in setting benchmarks based on 2017 program performance for 2018. If it appears that data inaccuracies may impact the quality of calculated benchmarks for certain measures, then CMS should notify all vendors and participants reporting those measures and not use them for payment calculations. If a clinician or group reports a measure that does not have benchmark data, then that measure should be removed from the MIPS composite score calculation and not calculated as a zero score that would negatively impact performance.

Submission Mechanisms

The ACC supports maintaining the current PQRS reporting mechanisms for MIPS reporting. In the initial years of MIPS, CMS should not only work to assist clinicians in the transition, but also vendors. CMS should work with its contractors to provide vendors with education on reporting requirements or system changes that need to be made in order to adapt to the MIPS changes.

While the College believes that the MIPS requirements for the 2017 reporting year will allow many vendors to continue their current data collection and reporting processes with minimal change, CMS should still closely monitor data submitted in the first years of the program for unintended discrepancies or data issues that may result from the program transition. Specific areas that CMS should closely monitor include: the impact of the Pick Your Pace reporting period options on the ability to create valid benchmarks for future years and the impact of benchmarking data based on submission mechanism. Any detected issues should be immediately communicated with affected vendor groups. CMS should then work with these vendors to identify the source of any issues, work together to develop a remedy, and work together to develop any communication which must be sent to clinicians to help them understand the impact of any technical data issues on their scoring. CMS and vendors must work closely together so that both parties can effectively assist clinicians and groups with MIPS reporting.

Qualified Clinical Data Registries

The ACC appreciates the continued recognition of participation in qualified clinical data registries (QCDRs) as a mechanism for receiving credit and reporting data across MIPS categories. As CMS further develops MIPS, policies should be developed to encourage and not hinder the growth of QCDR participation. The ACC requests that CMS consider the following comments in future MIPS rulemaking.

The annual self-nomination process for QCDRs continues to be burdensome. The self-nomination period occurs during the convergence of several CMS program deadlines, including the completion of the current reporting year, the filing of informal reviews, and preparation for the next reporting period. QCDR staff are inundated with assisting clinicians and practices understand requirements, checking data, and working on the self-nomination requirements. CMS should continue to work with QCDRs to determine a more reasonable cycle for self-nomination, measure selection, and reporting.

The QCDR self-nomination process should continue to permit QCDRs to voluntarily select those MIPS categories which it will report on. While the College recognizes CMS' desire to promote ways that clinicians and groups can efficiently report across all categories using one mechanism, some QCDRs may not be designed to report for categories such as ACI and IA. This should not disqualify them from being able to report data for any one MIPS category.

CMS must maintain the ability for clinicians and groups to report non-MIPS measures developed for QCDR reporting. The American Taxpayer Relief Act of 2012 permits QCDRs to develop quality measures outside of the Measures Under Consideration process required for PQRS/MIPS measures. The College is concerned that recent efforts by CMS and its contractors to eliminate "low bar" or "duplicative" measures threatens the ability for QCDRs to continue to implement the most clinically meaningful measures for the clinician and patient populations applicable to a specific QCDR.

The College recognizes that the intent of this process is to align measures so that clinicians and groups are not overwhelmed with multiple versions of a similar measure and to reduce the number of duplicative measures to improve sampling and data accuracy. However, QCDRs must maintain the autonomy to implement their own measures. For example, ACCPIN 4, which is reported through the American College of Cardiology Foundation PINNACLE Registry and Diabetes Collaborative Registry was deemed duplicative with PQRS Measure 326 (Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.)

The CMS performance measure is based on the previous guidelines from 2006 and 2011; however in *2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation* recommended that patients with nonvalvular AF, utilizes the CHA2DS2-VASc score for assessment of stroke risk (Level of Evidence: B). The rationale for CHA2DS2 -VASc is that other risk assessment models omit important risk factors, have low predictive ability, and categorize too many patients as intermediate risk, leaving the choice of anticoagulant or antiplatelet therapy to the discretion of the clinician.

The ACC supports the recommendation that CHA_2DS_2-VASc is better than $CHADS_2$ at predicting which patients with nonvalvular atrial fibrillation are at high risk for thromboembolism. CHA_2DS_2-VASc also appears to be better at predicting which patients are truly at low risk. Thus, broad use of the CHA_2DS_2-VASc scoring system could lower the number of patients treated with vitamin K antagonists who will not benefit from them and raise the number of patients treated with vitamin K antagonists who will.

The ability for QCDRs to report their own measures allows the ACC and others to implement measures that are more clinically meaningful and up-to-date than those measures that may be available in the MIPS measure set. CMS must work with QCDRs to determine a more feasible solution for aligning measures without stripping QCDRs of their ability to report non-MIPS measures.

Encouraging the Use of Electronic Reporting and Future Measure Development

The College supports the use of multiple submission mechanisms and a combined performance score early in the program to facilitate the use of electronic reporting and encourage the development of new measures. Permitting clinicians the choice of submission mechanisms to accommodate diverse practice environments, in combination with less restrictive scoring, gives clinicians the freedom to focus on effective use of CEHRT to improve patient care, as opposed to simply performing an activity to satisfy program requirements.

However, for CMS to be truly successful in encouraging new measure development, it is critical that CMS clearly define clinical data elements and data formatting constraints. Clinicians must be confident that the information collected and reported via Certified Electronic Health Records Technology (CEHRT) is both an accurate and meaningful representation of patient care.

Alternative Payment Models (APMs)

Snapshot Periods

The ACC supports CMS' approach to use several snapshot periods during the year, rather than one single point in time assessment to capture qualifying participants (QPs) within in APM. However, the final rule states that there will be three snapshot periods of March 31, June 30, and August 31 of the performance period. The ACC is concerned that this leaves out the potential for QPs joining in the last quarter of the year to become QPs. The College recognizes that the likelihood of clinicians joining later in the performance year and meeting the required payment and patient thresholds may be low, but still recommends that CMS include a December 30 snapshot date to ensure that all QPs during the performance year are captured.

MIPS Alternative Payment Models (MIPS APMs)

As stated in comments to the proposed rule, the ACC appreciates the flexibility provided to MIPS-eligible clinicians who participate in APMs that do not qualify as Advanced APMs. This flexibility however, creates additional complexity. Depending on the model a clinician or group participates in, MIPS scoring requirements and weights differ. Currently, many clinicians are unaware of whether or not they are participating in a given model. **In order for clinicians and groups to clearly understand which requirements apply to them, CMS must utilize a combination of clear communication, outreach, and direct feedback to groups and practices notifying them if they are participating in a model and the specific MIPS requirements that apply to them.**

APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

The ACC continues to oppose weighting the MIPS score for participants in models other than the Shared Savings Program and Next Generation Accountable Care Organization Model at 25 percent Improvement Activities and 75 percent ACI. For participants in APMs, the ACI decisions are likely to be determined by the entity and not by the participating clinicians. The ACC is also concerned that under

this weighting, clinicians are not being recognized for Quality, which should be the primary focus of patient care.

Advanced Alternative Payment Models

The ACC appreciates CMS' plans to expand opportunities for clinicians to participate in Advanced APMs. While this pathway may not be suited for all clinicians, it should not be completely unavailable to them. Clinicians should be able to consider options under this pathway that may suit their practice and patient population. The ACC supports CMS' intent to move forward with the development of additional voluntary models such as the Medicare Shared Savings Program (MSSP) Track 1+ ACO and the Bundled Payments for Care Improvement (BPCI 2.0) model for the 2018 performance year that would open up opportunities for more clinicians to participate in an Advanced APM. CMS should continue to take the approach of considering what current models can be amended to meet Advanced APM criteria. This would create an easier transition path for those currently participating in APMs to move into Advanced APMs that are based off of their current model design. Furthermore, CMS should continue to evaluate how mandatory models such as the proposed cardiac Episode Payment Models can be amended to meet Advanced APM standards.

Qualifying Participant (QP) Thresholds and Regulatory Waivers

The ACC remains concerned that even with the introduction of new specialty-specific Advanced APMs, the QP thresholds of 25 percent of Medicare part B payments for services furnished through the Advanced APM or 20 percent of patients attributed to the Advanced APM may still be high and restrict many specialists from QP status. The College understands that these thresholds are set in the MACRA statute and are outside of CMS' control.

The ACC appreciates that CMS has supported models such as BPCI that do not base attribution on evaluation and management services alone to determine the patient population under the model; this supports the concept that at times specialists may be leading care for a beneficiary, especially when that beneficiary presents with a specific disease or complex condition. CMS has also permitted regulatory waivers to promote the design of certain models. **CMS should continue to consider, with stakeholder input, how regulatory flexibility such as these two examples can be applied to future Advanced APMs to help specialists meet the QP thresholds.**

<u>Additional Guidance</u>

Throughout this comment letter, the ACC has identified areas where additional subregulatory guidance can greatly assist clinicians and groups in understanding the requirements of the 2017 QPP performance period. The ACC strongly recommends that CMS develop guidance in the following areas as soon as possible and distribute it publicly through the QPP website and other communications channels:

- Requirements for MIPS reporting based on reporting mechanism (e.g., claims, EHR, qualified registry, QCDR, CMS Web Interface, CAHPS for MIPS)
- Reporting requirements for the Improvement Activities MIPS category
- Additional guidance on the ACI category of MIPS, walking through the objectives of the category and what clinicians and groups must do based on their use of 2014 or 2015 edition CEHRT

- Targeted, separate, actionable guides for clinicians in the various MIPS flexibility groups (e.g., small practices, non-patient facing clinicians, MIPS APM participants) that clearly walk through their unique requirements and thresholds
- Clearer guidance on the Advanced APM QP determination process

In addition to the above resources, the ACC strongly encourages CMS to continue outreach to clinicians and specialty societies. Throughout the implementation year, CMS should regularly update its communications with answers to frequently asked questions that may arise as these policies are put into practice. The ACC also encourages CMS to continue to focus on ways to effectively educate Help Desk, quality improvement organization (QIO), Support and Alignment Network (SAN), specialty society, and vendor staff, as many clinicians and groups will be looking for live assistance as they navigate the QPP.

Conclusion

The ACC commends CMS for seeking input on this final rule that will impact the QPP policies for the 2018 performance year. The College recognizes the challenge that CMS has in effectively implementing the QPP in a way that promotes value-based care without disrupting the clinician's primary role of treating Medicare beneficiaries. The continued refinement of the QPP will require ongoing dialogue between CMS and the clinicians, patients, vendors, and other stakeholders affected by this program.

It is likely that unforeseen issues will arise as these policies are implemented. CMS must continue to keep an open and transparent line of communication beyond this final rule comment period. Should any issues arise that may result in unintentional consequences to clinicians, groups, or patients, CMS should communicate with stakeholders and act quickly to seek and implement resolutions.

The ACC appreciates the opportunity to comment on this final rule and looks forward to engaged discussion with CMS throughout the implementation of the QPP. If you have any questions or should require additional information, please contact Christine Perez, Associate Director, Medicare Payment and Quality Policy at cperez@acc.org or (202)375-6630.

Sincerely,

Richard A. Chazal, MD, FACC
President