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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.*

June 27, 2016

Andrew 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

Dear Acting Administrator Slavitt:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the proposed rule on **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-P)** as published in the Federal Register on May 9, 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 recognizes the challenges that the Centers for Medicare and Medicaid Services (CMS) faces in implementing a new payment system supporting the transition from volume to value. Even more challenging is to implement this system in a manner that is simple and flexible, while reducing the administrative burdens of the current Medicare quality reporting programs. The College accepts that the responsibility to transform the delivery of quality care is not CMS' alone. The new payment system proposed under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) reaffirms the importance of quality improvement and value as part of cardiovascular clinicians' commitment to professionalism. It will be crucial that cardiologists, members of the cardiovascular care team, and administrators work together to implement an infrastructure that supports care coordination, promotes accurate documentation of patient encounters and conditions, and provides clinicians with the resources needed to clearly understand their performance and how to best improve patient care and outcomes.

The ACC has provided extensive comments to this proposed rule based on the experience of our 52,000 physician, advanced practice professional, and cardiovascular practice administrator members. The College's comments also reflect our experience in the development of the National Cardiovascular Data Registry (NCDR) line of hospital-based and outpatient-care focused registries for quality improvement, the development of evidence-based performance measures, and the development of quality initiatives, clinical guidelines, and appropriate use criteria that support clinical practice improvements in cardiovascular care. Throughout the letter, our comments reflect the following themes:

- While the College appreciates the **flexible approach** taken by CMS' proposed policies for the Quality Payment Program (QPP), it has created a degree of **complexity**. It is crucial that CMS work with clinicians and practice administrators to ensure that they understand what reporting requirements apply and the thresholds they are being scored against. (i.e., whether they are in MIPS, a MIPS APM, or Advanced APM). CMS must also continue to seek ways to further **streamline and simplify** the QPP.
- The ACC remains concerned that **group-level reporting under MIPS and several APMs** may limit the ability for cardiologists to report the most meaningful measures, especially in a multi-specialty practice. The College asks CMS to continue exploring options either through changes to the scoring methodology or the ability to accept more than one data file per practice that would allow cardiology performance to be better reflected in the group score.
- CMS proposed the **Advancing Care Information (ACI)** component of MIPS as an improvement to the current EHR Incentive Program; however, the College believes that the proposed policies **lack the level of flexibility** requested by the clinician community.
- The Advanced APM path is open to very few Medicare clinicians, not only cardiologists. Under the MIPS APM list, there are very few specialty-focused APMs. CMS should work with societies to ensure that there are **opportunities for specialists to participate in APMs if they elect to do so**.
- The ACC supports **flexible MIPS reporting thresholds for small practices**, rural practices, and practices in health professional shortage areas. However, in the absence of other solutions such as virtual groups in 2017, CMS should monitor policies and provide effective practice assistance to these practices.

CMS must ensure that the implementation of these policies is aligned with effective clinical care delivery and does not disrupt the rich diversity of delivery venues and governance models among clinician practices. If the Quality Payment Program (QPP) results in a heavy burden on clinician practices and clinical autonomy, the College fears that it may result in limitations on Medicare beneficiaries' access to appropriate care. **The College encourages CMS and its contractors to maintain an ongoing dialogue with practicing clinicians and medical specialty societies beyond this comment period so that any unintended consequences of this new program are caught early. In the event that high reporting error rates occur, or there is a clear lack of understanding around program rules, the CMS should consider solutions such as holding clinicians harmless in the initial year of the program and phasing thresholds and requirements over time.** Together, CMS, medical specialty societies, practicing clinicians, and practice administrators must continue to develop and refine policies that truly support clinically-focused innovations in the delivery of high-quality, high-value patient care.

MIPS Eligible Clinicians

Low-Volume Threshold

Cardiology includes a diverse range of specialized clinicians, some of whom may be subject to the low-volume MIPS exemption. CMS proposes an exemption from MIPS requirements if a clinician “bill[s] Medicare less than or equal to \$10,000 within a performance year AND provide[s] care for 100 or fewer Medicare patients in that year.” That definition would likely exempt many cardiologists treating a primarily pediatric population, but who treat a low number of Medicare beneficiaries. However, that definition could still capture cardiologists who see relatively a small number of Medicare patients because of the higher costs involved in some cardiovascular procedures. **The ACC supports such a threshold, but recommends that CMS increase the dollar amount to \$30,000 and continue to monitor clinician specialties and subspecialties in various settings of practice and adjust this threshold as necessary in future years.**

Non-Patient Facing MIPS Eligible Clinicians

CMS proposes 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.” **The ACC supports exercising the Secretary’s discretion to specify different measure requirements and activities for clinicians considered “non-patient facing;” however, the College has concerns with the proposed threshold.** Within cardiology, this definition will most likely apply to those clinicians and groups primarily providing imaging services. It is common for full-time imaging specialists, even in academic and community centers, to have some service or on-call obligation that would cause them to exceed this threshold, even though the majority of their services are non-patient facing. **Alternative approaches One alternative approach would be to increase the patient encounter threshold above 25 encounters or to base it on a percentage of patients seen (e.g., 80% of services provided are determined to be non-patient facing). Other approaches include basing the threshold on claims or allowed charges (e.g., 85% of claims or charges are for non-patient facing services), or a combination of a patient and claims/charge threshold.**

Regardless of the final threshold, CMS must ensure that non-patient facing clinicians are appropriately identified. **The ACC supports the proposal to maintain a list of services that would qualify as “non-patient facing” services for purposes of this threshold. CMS should continue to update this list annually with stakeholder input.**

The ACC supports the flexibility provided for non-patient facing MIPS eligible clinicians; however, CMS should continue to keep in mind that most measures across the MIPS components apply to patient-facing encounters. CMS should work with medical specialty and subspecialty groups to determine how to best expand the availability of clinically relevant performance measures for non-patient facing MIPS clinicians, or ways to reweight MIPS scoring to provide these clinicians with credit for activities that more accurately align with their role in the treatment of a patient. Until additional measures can be developed and implemented, CMS should consider alternatives such as increasing the clinical practice improvement activity (CPIA) weight for non-patient facing clinicians and recognizing the extensive quality improvement practices performed as part of lab accreditation requirements.

MIPS Eligible Clinicians with Less than 12-Month Reporting Periods

CMS expects that clinicians with less than 12-months of data reported due to vacation, illness, or another leave of absence will have an insufficient sample size to generate valid and reliable MIPS scores. In this scenario, CMS proposes to score clinicians as meeting the CPS performance threshold, resulting in a zero

payment adjustment. **The College supports the proposal to hold clinicians harmless in all cases where they have insufficient data due to absence from practice.**

MIPS Category Measures and Activities

Submission Mechanisms

The ACC strongly supports the proposal to allow qualified clinical data registries (QCDRs) as a reporting mechanism for all three MIPS categories that require data submission by the clinician or group. Since 2014, CMS has accepted QCDR submissions for PQRS reporting and the College is pleased to see continued recognition of the value that QCDRs play in quality improvement.

As vendors become familiar with the new MIPS performance categories and requirements, they may not have the infrastructure to report across all MIPS categories in the early years of the program. **CMS should not require that health IT vendors, QCDRs, and qualified registries have the capability to submit data for all MIPS performance categories for recognition as an approved submission entity.** At least in the interim, these vendors should be required to be able to report at least one MIPS performance category. As CMS issues future rules regarding reporting requirements for each MIPS performance category, the vendor should have discretion to decide whether or not to offer data submission on more than one category. It will naturally be in the vendors' best interests to develop a "one stop solution" for MIPS reporting; there is no need for CMS to require that a particular reporting mechanism report all MIPS performance categories. This may unintentionally discredit vendors such as certain registries that are strong in quality reporting, but may not have the capability to capture data in other areas such as cost or ACI. However, if CMS is to eventually require that vendors report on all MIPS performance categories, then the College strongly encourages the Agency to phase in any new requirements over time to allow vendors to update their systems and processes accordingly. The College also supports CMS' proposal allowing clinicians and groups to report each MIPS category using a different submission method in 2017. This flexibility ensures that clinicians and groups can select the reporting mechanism that best fits their need in each category, while providing vendors time to develop more streamlined infrastructure and reporting solutions.

While the ACC supports the proposal to accept a different submission method for each MIPS category, the College strongly encourages CMS to go a step further and accept multiple submission files for a particular MIPS category from a practice reporting as a group. This is most crucial for multispecialty group practices. CMS has taken steps to allow clinicians to select the most clinically meaningful measures under the MIPS program. Yet it is unclear if this will actually be possible for clinicians practicing in multispecialty practices reporting as a group. Under the current system and as proposed, CMS only accepts a single data file per TIN for quality reporting. As a result, the group is motivated to select measures that apply broadly across the practice; typically primary care focused measures, rather than measures that reflect the care provided by each specialty in the practice. One solution may be to allow each specialty group within a multispecialty practice to report its own group data file. If this cannot be done under a single TIN, then CMS should explicitly encourage multispecialty practices that wish to report specialty specific quality measures and CPIAs at the group level to register each specialty group under a different TIN for identification purposes. While this approach would not be ideal as it may create greater administrative and contracting burdens or conflict with movement toward care coordination, practices would appreciate any clear guidance from CMS on what to do. The College recognizes that there may be operational challenges to implementing this recommendation and is willing to work with CMS and its vendors to develop the framework for the efficient collection and calculation of multiple data files for a single MIPS category from a group practice.

Cross-Cutting Measures

QCDRs should not be limited to the proposed cross-cutting measures list in order to fulfill the reporting requirements for cross-cutting measures. Subtle nuances in the practice of medicine may mean that the exact requirements, as specified in a measure, may not be met. **QCDRs should be permitted to report non-MIPS measures as cross-cutting measures.**

With regard to specific cross-cutting measures, ACC remains opposed to the Controlling High Blood Pressure measure (NQF 0018/PQRS 236) as it does not allow for clinical judgement or patient choice. At best, patients will be disregarded by the measure since their physician will be penalized if they decline an increase in treatment intensity, and at worst, patients may be put at risk for poorer outcomes. **In addition, NQF0005, #0006/PQRS 321 (CAHPS for MIPS Clinician/Group Survey) should count for more than one measure since it is administratively burdensome and requires a practice to bear the costs of a CMS-approved survey vendor.** As far as the remaining measures, CMS must assess their feasibility among the universe of clinicians.

High Priority Measures

CMS proposes to define a “high priority measure” as an outcome, appropriate use, patient safety, efficiency, patient experience, or care coordination quality measure. **The College supports the definition of a “high priority measure” as it is consistent with CMS’ ongoing messaging on measure priorities.** Reporting measures in these categories is currently incentivized, as most clinicians will have to report a measure in at least one of these categories in order to meet the current requirement to report across three National Quality Strategy (NQS) domains.

When defining appropriate use measures, CMS should not just focus on minimizing the overuse of services, treatments, or the related ancillary testing that may promote overuse. CMS proposes measures that “(1) reflect overuse of alternative treatments and services that were not evidence-based or supported by clinical guidelines; or (2) [measures] where the intent of the measure reflected overuse of alternative treatments and services that were not evidence-based or supported by clinical guidelines.” Measures and the scoring methodology applied to appropriate use measures should also be designed to avoid the unintentional encouragement of the underutilization of services, treatments, and testing, or inappropriate test substitution. The College encourages CMS to consider appropriate use measures that monitor the avoidance of procedures that are not required for a patient. These measures present challenges in their development and implementation; as a developer of AUC which can serve as the base for these measures, the ACC offers to work with CMS to determine ways to develop valid measures in this space.

As CMS looks to implement more measures across these high priority categories, the Agency should not require that clinicians report measures in specific categories beyond what is currently proposed (one outcome and one cross-cutting measure for most clinicians). The College believes that awarding bonus points for *voluntarily* reporting high priority measures under the MIPS quality category will encourage providers and measure developers to also prioritize the development and reporting of these measures. Maintaining this flexibility preserves the intent of the MIPS program to allow clinicians to select those measures that are most meaningful to their practice. It also allows specialties to continue developing and implementing quality measures based on clinical evidence rather than payment program requirements. Lastly, CMS should continue to recognize the value that process measures continue to serve in quality improvement. The ACC agrees that movement toward outcome measures is important; however, until a robust set of valid outcome measures can be developed across specialties and patient conditions, process measures must be maintained in order to support evidence-based practices that support quality patient outcomes.

Specialty Measure Sets

The ACC supports the quality measures proposed in the Cardiology Specialty measure set with the following exceptions:

- NQF 0067/PQRS 006 (Chronic Stable Coronary Artery Disease: Antiplatelet Therapy) should include aspirin and another antiplatelet agent similar to what is accounted for in NQF 0070/PQRS 007 (Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)).
- ACC and the American Heart Association (AHA) have recently submitted a measure for NQF endorsement on ACSVD. The ACC prefers this measure over PQRS 438, Statin Therapy for the Prevention and Treatment of Cardiovascular Disease. The ACC/AHA measure is NQF 2939, Statin Therapy in Patients with Clinical Atherosclerotic Disease. The ACC/AHA measure examines statin intensity, which is concordant with guidelines.
- NQF 70/PQRS 7 (Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)) cannot be reported in 2017 as three years of data are needed in order to report this measure. The Physician Consortium for Performance Improvement (PCPI), ACC, and AHA will advise CMS when this measure is appropriate for MIPS reporting.

MIPS Quality Performance Category Data Completeness Criteria

The ACC opposes the proposal to increase the requirements for reporting quality data from 50% of applicable patient encounters to 80% or 90% under §414.1340. As proposed, MIPS eligible clinicians and groups will fail the quality component of MIPS if those reporting via qualified registry, EHR, or QCDR do not report on at least 90% of all-payer patients that meet measure denominator criteria. The threshold for claims-based reporting is proposed at a threshold of 80% of Medicare Part B patients. Both of these proposed thresholds are a substantial increase from the current PQRS reporting threshold of 50% of applicable patients.

The ACC disagrees with CMS' rationale for these proposed increases. First, CMS states that the increased threshold will improve data accuracy by providing a larger sample size. While the College agrees that the higher reporting threshold will result in a larger sample size, CMS should emphasize other methods for improving data accuracy such as developing data validation plans with each reporting vendor, promoting the use of standardized terminology, and instructing clinicians and practices on proper documentation.

The College supports the proposed expansion of data collection to include all-payer patient encounters for all reporting mechanisms as a solution for improving sample size, rather than increases in the patient threshold. In the initial years of PQRS, CMS had originally proposed this higher reporting threshold, yet has continued to maintain the reporting threshold at 50% of eligible patients as an acceptable sample size. The ACC sees no reason to increase the reporting threshold under the MIPS quality component if 50% is currently an adequate sample size under PQRS.

Second, CMS states that the increased reporting threshold will discourage clinicians from “gaming the system” and cherry-picking the best patient cases to improve their quality score. The ACC is disappointed to hear that this concern was raised by stakeholders to CMS. In the College's experience, most practices and clinicians are spending most of their time trying to understand how to meet the minimum requirements of the current reporting programs, not on gaming the system. This is apparent through the 2014 PQRS Experience Report and 2016 Value-Based Modifier results, which show that most clinicians have either failed to meet reporting requirements or meet requirements enough to avoid a penalty, but have not been eligible for high-performance bonuses.

Application of Additional System Measures

The ACC supports the use of facility-level quality and cost measures for facility-based MIPS clinicians, as clinicians have some control over system-level performance. However, prior to implementing any facility-level measures into the MIPS program, CMS should work with measure stewards and affected specialties to ensure that measure specifications are appropriately aggregated to the clinician level and are reflective of those factors within the clinician's control. For this reason, the College appreciates that CMS is delaying implementation of these measures until additional comment and experience can be gained. In addition, reporting of facility-level measures should always be elective and not mandatory for clinicians and groups. CMS should also clarify the policy around these measures to indicate whether hospital-based clinicians would be permitted to report these measures, or if they would only be available to hospital-employed clinicians.

To promote the implementation and reporting of facility-level measures, CMS should explore the feasibility of using hospital-level clinical data registries such as the National Cardiovascular Data Registry (NCDR) ACTION Registry for heart attack care as a data source and reporting mechanism, similar to the QCDR pathway that is currently available for the reporting of clinician-level quality measures. The ACC would welcome the opportunity to work with CMS on this solution.

Global and Population-Based Measures

CMS should eliminate the claims-based global and population-based measures derived from the Value Modifier as part of the MIPS quality score. CMS states 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. The College recommends better ways to promote care coordination and population-level care through additional credit for clinical practice improvement activities and quality measures focused on population-based care.

If CMS implements these measures as proposed, the ACC supports the proposal to limit the all-cause hospital readmissions measure to groups of 10 or more clinicians, as this measure has not been statistically valid for solo practitioners and groups of less than 10. The College also supports applying the requirements of 200 eligible cases. CMS should continue to monitor the statistical validity of these measures and increase sample sizes when necessary.

In addition, the Agency must be more transparent in the application of the global and population-based claims reporting quality measures applied to the CPS. Recent education provided by the Agency does not make it clear that clinicians will be scored on the composite measures of acute and chronic conditions and potentially the all-cause hospital readmissions measure based on group size.

Selection of Quality Measures for Individual MIPS Eligible Clinicians and Groups

The ACC supports goals stated in the proposed rule as well as the CMS *Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)* to seek efficiency and alignment in the development and implementation of new quality measures under MACRA. The College encourages CMS to keep measure developers, clinicians, and stakeholders engaged in the quality measure development and selection process to ensure the implementation of clinically meaningful measures that are aligned across the MACRA Quality Payment Program performance pathways and other payer programs. The ACC looks

forward to continuing to work with CMS, Americas Health Insurance Plans (AHIP) and others through the Core Quality Measure Collaborative as well as other forums to promote the use of quality measures reflecting evidence-based cardiovascular care.

Peer Review

While the College agrees with the transparency and review of measures in a peer-reviewed environment, several outstanding questions remain. It is not entirely clear how the process would work, including timeframes and how the agency plans to notify the public that the measure has been submitted to a journal. Journals vary in their timelines for review, which may affect how quickly a measure may move forward in the process. Additionally, journals may not necessarily be equipped to review or accept papers on performance measures. It is also not clear as to how the agency will decide which journals will be selected, and whether the article must be accepted for publication as well.

CMS should use the Call for Quality Measures process as an opportunity to gather the information necessary to draft the journal articles required for quality measures implemented under MACRA. Maintaining this cycle will provide a predictable timeframe in which measure developers must submit information to CMS. When possible, any information required for journal article submission should align with the information required for the submission of the measure to CMS to reduce the workload of this new requirement on measure developers.

Resource Use Performance Category

The ACC is pleased that MACRA phases in the resource use category weight over time, starting at 10 percent of the composite performance score (CPS) for the 2019 payment period. This will allow time for CMS to work with stakeholders to refine and develop episode groups that reflect real-world clinical care and patient scenarios, as well as improve current attribution processes. As CMS continues its work on the development and implementation of episode groups for cost measurement, the ACC strongly urges CMS to involve practicing clinicians throughout these processes beyond the current public comment periods required by MACRA.

Value Modifier Cost Measures Proposed for the MIPS Resource Use Performance Category

CMS proposes at §414.1350 to utilize the total per capita cost measure, Medicare Spend Per Beneficiary (MSPB) measure, and episode-based measures for resource use measurement for the 2017 performance period. **The ACC continues to believe that there are issues with use of the total per capita cost measure and the MSPB measure, as these measures are designed to measure cost at the hospital-level, not the clinician-level.** As a result, some clinicians may be attributed to care and conditions that are outside of their control. The ACC recommends elimination of the total per capita cost measure and the MSPB measure for resource use measurement.

Episode-Based Measures Proposed for the MIPS Resource Use Performance Category

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. Although these groups may serve as better methods for measuring resource use than the current hospital-level measures, the College strongly urges CMS to proceed cautiously with the development and implementation of new episode groups. No episode groups should be implemented for payment determinations until they have been tested and reviewed for potential unintended effects. The College is concerned that implementation of new episodes without conducting this review may result in clinicians being unfairly penalized for treating high-risk patients due to flaws in the episode's procedure

and diagnosis coding, attribution, and risk adjustment methodology. Prior to the implementation of any episode upon which a clinician or group may be scored, CMS should include the episode on feedback reports for a full calendar year as informational only so that clinicians can be familiar with the episode of care and assist CMS in identifying any issues before it is implemented.

With regard to specific episodes, the College recommends that CMS only implement those episodes included in the 2014 sQRUR for the 2017 performance period. No additional groups should be implemented until CMS has concluded the current public comment process and approved any new groups with practicing clinician input. Under the Cardiovascular episode list, these include: AMI without PCI/CABG; Aortic/Mitral Valve Surgery; AFib /Flutter, Acute; CABG, Heart Failure, Acute; Pacemaker; and PCI. CMS has identified the challenge of preparing for MIPS when no MIPS data is available. Limiting the 2017 episodes to those currently included in the sQRUR will help alleviate this issue as practices will be able to use their current reports to understand these episodes and prepare for performance under MIPS.

The ACC continues to hold concerns about the development and implementation of episodes for chronic cardiovascular conditions, particularly heart failure, atrial fibrillation, and ischemic heart disease and opposes implementation of any chronic condition episode until CMS has had the opportunity to review and refine these and any other new episodes through the current public comment period with practicing clinician involvement. Disease progression is variable among patients and is often impacted by factors outside of the clinician's control. Among chronic ischemic heart disease patients alone, not all patients are the same. Some patients will have prior coronary artery bypass grafting (CABG), prior percutaneous coronary interventions (PCI), varying degrees of reduced left ventricular ejection fraction (LVEF), and/or a variety of comorbidities. Depending on the patient, it may be appropriate to pursue other therapy and evaluate the patient's response before determining that the most rapid and aggressive treatment is needed. The combination of these factors makes it extremely difficult to design a "baseline" episode group for chronic conditions.

Chronic condition-based episodes also increase the potential for a patient to fall within simultaneous episodes. For example, a patient with chronic heart failure is likely to suffer from other chronic conditions, plus undergo various procedures. This creates a web in which services must be sorted and attributed to the proper episode and clinician. In cases where a patient is admitted with two chronic conditions, such as heart failure and atrial fibrillation, heart failure may precipitate the atrial fibrillation, or the atrial fibrillation with rapid rates may precipitate the heart failure. In this instance, it is unclear which episode and clinicians the admission will be attributed to. In order to simplify the MIPS resource use category, the ACC recommends that no chronic condition episodes be implemented until they can be further developed.

Scoring the Resource Use Category

In addition to the above recommendations, the ACC requests clarification on the calculation of the resource use score. The proposed rule states that clinicians or groups will be scored on an average of "all resource use measures attributed to the MIPS eligible clinician." Based on this methodology, there may be a large range in the number of measures reported by each clinician for this category. For example, there may be clinicians scored on only the MSPB and total per capita cost measures and no episodes, as well as clinicians scored on these two measures plus a large number of episodes. CMS should monitor whether the methodology creates any advantages or unintended disadvantages for clinicians who have a greater number of applicable episode-based measures versus those who have few or none.

Clinical Practice Improvement Category

The ACC supports the flexibility and menu-based approach proposed for the clinical practice improvement category (CPIA). The College also supports the proposal to base this performance category on attestation that can be submitted via qualified registry, EHR, QCDR, CMS Web Interface, claims, or another attestation data submission mechanism. Providing several options will ensure that clinicians and groups will have a way to submit their CPIA data even if their current quality reporting mechanism does not intend to offer CPIA submission in 2017. As CMS implements new CPIAs in future years, the College supports a process similar to the current CMS Call for Quality Measures and recommends that CMS clearly communicate the timelines and requirements to the public early and often to allow for the preparation of submissions.

Submission Criteria

CMS proposes that most clinicians could achieve a total of 60 points based on participation in high, medium, or low weight activities. This results in a requirement that clinicians participate in two to six activities in order to receive full credit for this category. Given the broad list of CPIAs provided in the proposed rule, this is an appropriate threshold; however the College provides several recommendations to prevent this category from being a burden to clinicians and groups.

First, the College supports the flexibility given to clinicians and groups in small and rural areas, geographic Health Professional Shortage Areas (HPSAs), and non-patient facing clinicians. CMS proposes that clinicians or groups in these categories only report two CPIAs to receive full credit. However, the College recommends that CMS remove the requirement that these activities be either medium or high weight (20 to 30 points) at least in 2017. While the College believes that two medium or high weight activities may be achievable by these practices, many will be deluged with the task of understanding and implementing the base MIPS requirements in 2017. If CMS does not consider allowing these clinicians and groups to report two activities of any weight, then CMS should listen to these practices as the final regulations are implemented and determine whether or not hardship exemptions or additional flexibility will be needed.

Second, the ACC supports the flexibility proposed for MIPS clinicians or groups that are participating in an alternative payment model (APM) and are not Qualifying Participants (QPs) in an Advanced APM or partial QPs who elect not to report MIPS. CMS proposes that clinicians under this scenario only need to achieve 30 points for full CPIA credit. The College supports this incentive for APM participation, as these clinicians are likely engaged in other practice improvement activities linked to their model. With both the small practice and APM flexibility, it will be crucial that CMS provide these clinicians and groups with feedback on whether or not either of these exceptions applies. The College strongly believes that the success of the Quality Payment Program under MACRA will be based on the ability of clinicians and groups to understand exactly what requirements apply to them during the performance year.

CPIA Inventory

The ACC appreciates the broad list of over 90 activities listed as eligible CPIAs as well as CMS' intent to update this list on an ongoing basis. The College provides the following comments to ensure that this new performance category is implemented to reflect the flexibility intended by CMS.

The ACC strongly supports the recognition of the role QCDRs play in quality improvement across all subcategories of CPIA. The College supports the wide range of activities linked to QCDR use and encourages CMS to maintain these in the final rule. However, the College recommends that CMS replace references to “QCDR” with “clinician-led clinical data registry” as defined by the

Improving Health Information Technology Act (S. 2511). Use of clinician-led clinical data registry will allow clinicians to receive credit for their participation in hospital-level registries, which, while they are not QCDRs according to the statutory definition, still achieve the same quality improvement and population health management goals as QCDR use. Use of this term will greatly assist those clinicians who primarily perform hospital-based services and procedures.

If CMS does not adopt the term clinician-led clinical data registry, then at a minimum, the College recommends revision to the following Population Management activity that references non-QCDR clinical data registries. Not all clinical data registries are linked to use of a QCDR, but still provide data that is used for quality improvement. Requiring that this activity include use of a QCDR would run counter to the intent to recognize participation in registries beyond a QCDR.

Subcategory	Activity	Weight
Population Management	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR <i>registry</i> data for quality improvement (e.g., comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).	Medium

Starting in 2018, the ACC will have many members participating under the appropriate use criteria (AUC) mandate for advanced imaging required by §218(b) of the Protecting Access to Medicare Act of 2014. **CMS states that clinicians required to consult with clinical decision support under this mandate “are encouraged” to select CPIAs other than those related to the use of clinical decision support. The College urges CMS to maintain this statement as a recommendation and not require that a clinician or group report another CPIA if they are participating under the mandate and report a CPIA related to clinical decision support.** The intent of the mandate is to improve the delivery of clinically appropriate care, which is aligned with the intent of the CPIA category. Use of clinical decision support and AUC will be a new part of the workflow for many clinicians and groups including cardiologists, radiologists, and primary care clinicians when the mandate goes into effect. It will require both time and resources to learn and implement these into practice.

This concept should also apply to participation in other quality improvement activities required by federal or state law. Many clinicians, including those performing cardiovascular imaging procedures fulfill extensive quality improvement activities as part of lab accreditation requirements. These clinicians should receive credit for efforts taken to manage the appropriate and safe provision of services, even if performing these activities is required by law. **CMS should recognize participation in lab accreditation activities and other required initiatives as CPIA if they contribute to the overall quality and safety of patient care. CMS may continue to “encourage” clinicians to select other**

CPIAs but should not require that clinicians select other activities which may pose an additional burden or may even be unnecessary in light of other substantial clinical practice improvement activities that the clinicians are engaged in.

The College recommends that CMS provide additional guidance on the CPIAs finalized through communication such as the CMS website and MLN updates, as well as through direct feedback to clinicians and practices. While the College appreciates the broad menu of activities, some are clearer than others. Participation in the Million Hearts Center for Medicare and Medicaid Innovation model activity is an example of a clear activity. In contrast, it is unclear whether the “Use decision support and protocols to manage workflow in the team to meet patient needs” activity under Patient Safety and Practice Assessment should be reported by those clinicians reporting activity related to the AUC mandate. Likewise, it is unclear whether or not a clinician or group participating in a QCDR would have to provide additional information at attestation, or potentially at audit, to prove which QCDR-related activity they are reporting. This is especially a concern as several of the QCDR-related activities carry different weights. While the College does not want CMS to be overly prescriptive or require additional requirements beyond attestation, additional guidance and feedback to practices would be helpful to ensure that they are correctly tracking their progress toward a complete CPIA performance score.

CPIA Scoring

As stated above, the ACC supports the menu approach to achieving points under CPIA. The ACC also supports the proposal to score clinicians and groups based on participation in and attestation of CPIAs rather than any measurable improvement. While measuring improvement through CPIA participation is an interest of CMS, the College cautions against potential unintended consequences this may cause. There may be many activities that contribute to patient care, but are not linked to any validated metric for measuring quantitative improvement resulting from the specific activity. If measurable improvement is to be proposed in future years, the College is concerned that this may disqualify many CPIAs from this component and may stifle the innovation of best practices to improve patient care.

In addition, as CMS assigns weights to different activities, the College strongly encourages the Agency not to limit high weight activities to those that support the patient-centered medical home. There are many activities performed by specialists that may not be recognized under the patient-centered medical home model. CMS should work with specialty societies during its ongoing update of the CPIA list to determine whether there are specialty-specific activities that should be highly weighted.

MACRA awards full CPIA credit to clinicians participating in a certified patient-centered medical home or comparable specialty practice. While the ACC appreciates the recognition of “comparable specialty practices” under this definition, CMS should look beyond specialty medical homes such as those accredited by NCQA, The Joint Commission, and URAC. There are many cardiovascular practices participating in initiatives such as SMARTCare that involve activities supporting patient-centered, coordinated, quality-focused principles similar to what the medical home model promotes. **As the medical home model may not fit all specialties, CMS should consider expanding the CPIA full credit provision to clinicians participating in other specialty practice initiatives intended to achieve the same goals.**

Concerns with Group Level Reporting

Similar to quality scoring, the ACC is concerned that group level reporting as it is currently structured may not recognize the contributions of specialists within a multi-specialty practice or institution. The current scoring may incentivize these larger practices to select broad CPIAs that may not apply to the specific care provided by the variety of specialists in the practice. CMS should consider ways to

recognize and promote specialty-specific CPIAs either through scoring incentives or the ability for specialists to receive credit for their specific CPIAs that may not be reported at the group level.

CMS Study on CPIA and Measurement

The College supports CMS' proposal to conduct a study on CPIAs and quality measurement to understand clinical quality workflows and simpler data capture related to quality measures. CMS proposes that clinicians and practices participating in this study will receive full CPIA credit. When CMS solicits participants for this study, the Agency should ensure that a diverse range of participants is selected including those across different specialties, small practices, rural areas, private practice, and those reporting quality data via each of the different reporting options, including QCDR. This will ensure that any recommendations take into account the different workflow and priorities of each of these populations.

Request for Comments on Use of QCDRs for Identification and Tracking of Future Activities

The College appreciates the recognition of QCDRs as a submission mechanism for CPIA. In particular, the ACC supports the use of QCDRs as a potential mechanism for the implementation of clinically meaningful activities and the impact that these activities may have on long-term patient outcomes and improvement. The College supports the proposal to allow QCDRs to define specific CPIAs for specialty and non-patient facing MIPS eligible clinicians and groups through a flexible process similar to the one already established for the introduction of non-PQRS/non-MIPS quality measures implemented through a QCDR.

Advancing Care Information/Health Information Technology (Health IT)

In recent years, health IT has been perceived as having the potential to serve as the underpinnings of a reformed healthcare delivery system, and MACRA is the first statute to treat it as such. MACRA explicitly ended the standalone electronic health record (EHR) program and connected it to performance measurement and healthcare delivery. The College applauded Congress' efforts to do so, in large part, because it recognized that health IT was a vital component of improving the quality of patient care and offered the opportunity to address the multitude of problems with the Medicare EHR Incentive Program. Unfortunately, the ACC believes that the regulations as proposed by CMS do not follow through on that promise. Instead, the proposal essentially continues the Medicare EHR Incentive Program for physicians, along with all its problems, and applies it to other categories of clinicians, with a few minor changes. These changes do not ease the burdens imposed on clinicians, nor do they truly move the healthcare system forward along the path towards improving care. Yes, more clinicians and hospitals have adopted EHRs since the implementation of the federal EHR program, but the true question is whether this has been done in a manner that will actually have a positive effect on patients either in the short or long term. To date, the answer has been a resounding "no."

Health IT surveillance

As with all new medical tools and devices, continued surveillance of health IT products on the market is crucial to ensuring patients continue to receive the highest quality care. The most critical component of patient care is the patient visit, and yet clinicians today have little time to spend with patients, discussing their concerns, because of the vast array of administrative burdens that have been imposed coupled with pressures of declining reimbursements. The mere mention of a new requirement to be imposed on clinicians amplifies those existing concerns. **To alleviate such concerns, the College recommends that CMS develop a mechanism that would allow clinicians to use their EHRs to report such concerns.**

At present, CMS' proposal for health IT surveillance is ill-conceived at best. By their very nature, surveys are imperfect recall instruments, and allowing CMS (or its designee) access to an EHR or related records is not always as simple as it appears, given EHR system complexities and the difficulties associated with allowing outsiders access to EHRs that have nothing to do with HIPAA restrictions. For instance, some EHR vendors charge a licensing fee and limit the number of EHR system users. Others, particularly those that are cloud-based, make it difficult to access records without additional permissions. And there is an additional burden associated with hosting an auditor for a period of time, regardless of the anticipated length of the visit. Essentially, CMS has proposed the creation of yet another audit program that will likely have its own requirements and timelines for responding and penalties for failure to comply – intentional or otherwise – and adding to the Medicare program's complexity and clinician confusion regarding requirements. Rather than creating an entirely new program that creates additional complexity and burdens for clinicians, the College recommends the development and implementation of an "easy button" for reporting incidents associated with health IT or EHRs themselves that would alleviate some of the burden and reduce the risks associated with recall. Instead, such an approach could capture exactly what the clinician is doing at the time the problem occurs – an approach that is already common in IT systems for debugging purposes. The output could be reported to both the health IT vendor and ONC (or its designee), simplifying the process and alleviating the burden on clinicians.

Information blocking

Information blocking has been a significant impediment to the development of an interoperable healthcare environment. The breadth of this problem has been well-documented in congressional hearings, as well as the report from April 2015 by the Office of the National Coordinator for Health IT (ONC). What has also become clear from this research is that the overwhelming majority of the information blocking is perpetrated by vendors – EHR and otherwise, not clinicians. In fact, most clinicians do not even know what information blocking is; they only know a problem exists when they are unable to obtain access to their patients' medical records. For instance, cardiovascular specialists interested in joining ACC's National Cardiovascular Data Registry for quality improvement have been quoted exorbitant fees to allow access to their own patients' records for such purposes. As with the Agency's proposal to conduct health IT surveillance, the ACC recognizes that there are programmatic reasons and good intentions behind CMS' proposal to require that clinicians attest that they are not engaged in information blocking.

However, given the rarity of the situation in which clinicians are the perpetrators of such actions, the College opposes CMS' proposal to require clinicians to attest that they are not engaging in information blocking, a proposal that could subject them to significant financial and professional penalties should they use certified EHR technology that is engaged in such practices unbeknownst to them.

Instead, the ACC supports efforts to prevent vendor information blocking through the use of the ONC EHR certification program. This will allow CMS and ONC to ensure that vendors, the entities that stand the most to gain from information blocking, are unable to do so. Additionally, where there are concerns of information blocking outside of the vendor community, they are generally committed by integrated health systems, hospitals or medical practices, rather than by individual clinicians. For example, because each hospital requires the use of a particular laboratory, physician practices must implement as many as six different interfaces simply to order patients' labs and to ensure that the results are received. Many systems are still unable to process bi-directional orders. As such, individual clinicians should not be held responsible for actions taken by the entity, particularly in situations where the clinicians are employed, as they would be if they are required to individually attest to not engaging in information blocking. **The College recommends that CMS require entities to attest that they do not and will not engage in information blocking as part of the Medicare enrollment process. This will allow CMS to hold responsible the entity and individuals actually responsible for such behavior,**

that is, the owners, managing directors and other individuals with control over the enrolling entities behavior.

Advancing care information (ACI)

The College continues to support the rational use of health IT to improve the quality of patient care. The promise of health IT, still undelivered, is a connected system that allows clinicians to easily share appropriate information about common patients, as well as to learn from patients about how to improve the quality of care they receive, to improve the US healthcare system as a whole. Rather than evaluating the use of health IT to improve the quality of patient care, the proposed program continues to rely on crude metrics regarding the use of an individual's EHR. It does nothing to pressure EHR vendors to develop products to improve clinical care and care coordination. Because of these concerns, as well as the host of concerns expressed in the ACC's comments on Stages 1, 2 and 3 of the EHR Incentive Program that continue to apply because of explicit determination by CMS to draw from those efforts, the College has serious reservations about the ACI component of the MIPS program.

Terminology

It is clear that CMS is distancing itself from the term "meaningful use" (MU) as much as possible as it renames the MU Incentive Program for physicians to "Advancing Care Information." While ACC understands the sentiment – and the connection between the new name and goals for health IT, the College believes the Agency is drawing a distinction without much difference, one that is bound to cause a great deal of confusion. The term "meaningful user" is still retained in the statute, as well as in the regulation. Additionally, no changes have been made to the hospital or Medicaid programs of the same name, and the initial proposal does not alter CMS' modified Stage 2 or Stage 3 regulations significantly. In fact, it explicitly incorporates the finalized objectives and measures from those regulations. **As such, the College opposes the name change and urges CMS to revert to referring to the health IT component of the MIPS program by its previous name or one very similar.**

Clinical Quality Measurement

The College supports CMS' proposal to remove clinical quality measure reporting from the ACI component of MIPS. This change represents the alignment of quality reporting programs promised by the Health Information Technology for Economic and Clinical Health (HITECH) Act and eliminates unnecessary burden and duplication of reporting. Clinicians were, by-and-large, forced to report the same or essentially the same measures to meet the requirements of multiple programs. The proposal moves away from that model and focuses separately on evaluating clinicians for their performance on clinical quality reporting once.

Performance Period

CMS proposes that the performance period for a brand new program should be the full calendar year, regardless of changes to the program, a position contrary to that which Congress has clearly supported over the last several years. Congress – and the Agency itself at times – has supported that years where significant changes have been implemented for programs and where clinicians are new to a program, expectations should be lowered and set at a 90-day performance period. Yet, in this proposal, CMS suggests that with only 60 days' notice, clinicians should be able to report ACI data for a full calendar year. This is simply impracticable. The typical 60-day notice period required by the Administrative Procedures Act does not account for the technology development and implementation cycle. Both vendors and clinicians will need time to digest the final regulations and implement the required changes in technology, mapping and workflow for 2017. **Even where medical practices have already adopted the**

requisite CEHRT, it will take time for clinicians to understand the new requirements and to implement any changes in workflow. Going forward, CMS must understand that even minor changes to the program require vendors to make adjustments to systems and practices to implement those adjustments. **As such, ACC urges that CMS reconsider the full calendar year performance period for the ACI component of MIPS.** To address these concerns, the ACC recommends that CMS adopt a 90-day reporting period for the ACI component of MIPS. **At a minimum, the College urges CMS to adopt a reduced reporting period to allow for redress of problems created by the changes in regulations and adjustment to new requirements. Specifically, for years where the Agency has made significant programmatic changes, the certification requirements have been altered significantly, and clinicians are subject to MIPS for the first time. , the College urges CMS to adopt a 90-day reporting period to allow for redress of problems created by the changes in regulations and adjustment to new requirements.**

Certified EHR technology

CMS proposes to allow clinicians flexibility in their choice of EHRs based on certification year for 2017. The ACC supports this proposal, enabling clinicians at least one area where their transition into the new program might be relatively smooth. However, the College does have some concerns regarding the requirement to implement an EHR certified to the 2015 Edition in 2018. At this time, there are no EHRs listed in ONC's Certified Health IT Product List that are certified to the 2015 Edition. There are press reports that EPIC has received certification and there are approximately 12 others at some point in the testing and certification process. This represents only a small fraction of the EHRs currently implemented in physician practices, means that clinicians are once again dependent upon vendors to determine that the EHR certification requirement imposed upon physicians and hospitals is a compelling enough business case to compel them to make the changes needed for 2015 Edition certification. Where vendors make the decision that it is not worth the financial risk, clinicians will need to migrate to entirely new systems. Even where the vendor decides to invest in the upgrades, clinicians will be competing with others to have the upgrades implemented in time. Because everyone must meet the same requirements, all clinicians will be competing for the same limited resources to ensure that their upgrades or new systems are implemented in time. **Given these concerns, the ACC urges CMS to take a cautious approach to requiring 2015 Edition Certified EHR technology be implemented in 2018, ensuring that clinicians are not penalized by the failure of EHR vendors to allow sufficient time and resources for developing, certifying and implementing upgraded systems. Rather than explicitly establishing this as a requirement for 2018 as part of this rulemaking, the College recommends that CMS state its intention to do so, but allow for flexibility in the event that a large majority of the vendors do not have their systems recertified in sufficient time for implementation of the upgraded systems by physician practices.**

Group Reporting

Although CMS issues its proposal on ACI measurement for individuals in group practices as one on the subject of group reporting, in actuality, it is a proposal for group scoring, a question that is more complicated than the length of the preamble discussion on it indicates. To date, clinicians have been measured based on their own performance – or at least the performance attributed to them as best measurement allows at this time. Here, CMS proposes to allow groups to elect to be measured on their ACI success based on the performance of the group as a whole.

While the College agrees with CMS on the importance of enterprise-level continuous improvement strategies and enterprise-wide health IT adoption, the ACC is concerned that group-level scoring has never been tested as part of the Medicare program. To address this question, the College recommends that the Agency engage in further conversations with relevant stakeholders such as medical

specialty societies to whether enterprise-level scoring makes sense and, if so, determine the most appropriate method for implementation. At the very least, the ACC recommends that group-level reporting for the ACI component of MIPS be an option as opposed to a requirement. Additionally, the College emphasizes the importance of providing clinicians with individual feedback promptly, even if they are scored based on their group's overall performance to emphasize the role that each individual participant plays in determining the group's performance and to allow each clinician to benchmark individual performance against the group's performance.

As in the past, the College continues to support the availability of batch reporting methods for group practices.

Scoring Methodology

Under the statute, the ACI component would comprise 25 percent of the MIPS composite score. The statute also allows for the Secretary to reduce this percentage where the proportion of eligible professionals who are meaningful EHR users is 75 percent or greater. Assuming CMS finalizes its proposal for voluntary participation by advanced practice professionals, the Agency's proposal to base this percentage on physicians makes sense. However, should CMS make participation by other categories of clinicians mandatory, ACC would recommend including them when determining the percentage of meaningful EHR users.

The College, the American Medical Association and many other medical specialty societies have long called for increased flexibility in the federal EHR Incentive Program. The current all-or-nothing approach penalizes clinicians for their efforts to implement certified EHR technology if they do not meet all of the requirements. CMS professes to have listened to this feedback and responded; however, the approach proposed is not significantly improved. The Agency claims that this is no longer an all-or-nothing program. However, with a requirement that minimum thresholds be met before any score is awarded, the program retains all-or-nothing aspects. **The ACC opposes the proposed approach and urges CMS to develop an EHR program that truly rewards clinicians for their efforts to adopt health IT.**

Under the current proposal, the ACI score would comprise two components: a base score and a performance score. The base score would include reporting on 11 measures with a threshold of one or the appropriate answer to a yes/no measure and total one-half of the ACI score. The performance score would be based on eight measures and offer flexibility in terms of focus because while the total point possible would be 80, the maximum would really be 50. However, a clinician's performance score would be irrelevant if one requirement for the base score was missed. Given this, it is hard to argue that the Agency has truly moved away from an all-or-nothing approach to health IT implementation. If CMS was really interested in doing so, its proposal would recognize clinicians' efforts across the board. Missing one element should not cost clinicians to the extent that it would under this proposal. Instead, the College urges CMS to move to a scoring methodology that rewards performance.

Base Score

- a. Removal of measures

The College supports eliminating the requirement for measuring computerized provider order entry (CPOE) and clinical decision support (CDS). CPOE is fundamental to implementation of EHRs into the clinical workflow. It is impossible to be truly using the EHR and not to use CPOE. As such, it is unnecessary to require tracking and measurement of a clinician's use of CPOE. Instead, it becomes merely one additional burden imposed upon clinicians. CDS is also an unnecessary burden on clinicians, but for vastly different reasons. Many current CDS tools are not developed to the extent needed to follow

through on their promise of improving clinical care. Today's tools often generate pop-up screens that lead to fatigue, as has been demonstrated through numerous studies. Instead, clinicians click through them without the critical information truly registering. The use of CDS is best included as a potential clinical performance improvement activity (CPIA) that includes flexibility for tool improvement, rather than as an ACI requirement.

b. Security risk analysis

Under CMS' proposal, all clinicians would be required to conduct a security risk analysis. The College understands the concerns and strongly supports the implementation of a privacy and security framework that minimizes the risk of privacy or security breaches in medical practices and hospitals. The ACC supports the call for performing security risk analyses annually upon installation or upgrade and throughout use of EHRs. However, the ACC is concerned by reports that small practices in particular have difficulty with this measure. Components of the assessment are difficult to interpret, and often, practices are uncertain as to what they are attesting. The College suggests that CMS establish an educational campaign to help physicians better secure and protect patient information in a digital world to reduce the likelihood of breaches. This would help program participants to better understand the importance and utility of the administrative, physical, and technical safeguards which are required to be implemented, along with items such as audit logs. **If CMS insists on requiring the implementation of this particular measure to assess risk, the College urges CMS to provide clinicians with the necessary and appropriate resources for not only assessing said risks, but for also addressing any problems identified as part of that assessment.** These resources should include but not be limited to assistance in assessing the risk, funding for hiring external expertise as needed and the development of guidance and other resources that will enable practices to further protect patients. Experience has demonstrated that it costs a great deal more, on a per clinician basis, to achieve security in a small practice than in a large practice or hospital. As such, the relief program would need to be scaled appropriately. Additionally, the College suggests that CMS provide additional insight into the audit requirements of this objective, given the difficulties program participants have had in meeting and supporting their work towards this objective.

Performance score

Should clinicians manage to meet all of the requirements for the base score, they move on to the performance component of the score. The flexibility provided in this component is appreciated and better reflects the sorely needed flexibility, particularly in such a complex program. The ACC supports such an approach. However, there is one component of its proposal that CMS neglected to fully explain. The proposal states that clinicians will be scored based on their performance, but it never details how performance will be determined. Will there be a threshold requirement? Will it be based on the number of times the clinician is successful as compared to the number of potential times the clinician could have performed the measure (numerator/denominator)? **The College urges CMS to clarify how scoring for the performance score is ascertained.**

One other concern that the College has regarding the performance score is the terminology. CMS refers to ACI as a performance category and the performance category score and then talks about a performance score for only one component of the category score. The College recommends that the Agency not use the word "performance" in both instances to reduce the opportunities for confusion.

Perhaps even more important than the aforementioned concerns is whether true flexibility exists. As described below, there are significant problems with the measures that CMS proposes to adopt for the ACI. Given the magnitude of these problems, clinicians may struggle to meet the requirements through no fault of their own, but rather, owing to deficiencies in the state of Certified EHR technology and the

nationwide health information system, as well as the unwillingness/disinterest of patients to engage with their clinicians and health information electronically. **The College opposes efforts to penalize clinicians for matters beyond their control, as well as provisions that require them to impose requirements upon their patients to engage with their health information electronically, despite clear wishes not to, solely for the purpose of meeting Medicare’s payment requirements.**

Objectives and measures

MACRA presents CMS with yet another opportunity to re-envision the government’s approach to health IT adoption, and again, the Agency fails to do so. The health IT component of MIPS should be designed to focus on the core issues facing the health IT industry: a lack of interoperability and EHR usability. In order to achieve this, CMS should return to the statutory intent and focus the program on the component of health IT that continues to lag: usability, information exchange and quality improvement. The measures of the program must prioritize outcomes and use cases rather than processes and data entry. Therefore, redesigned measures would focus on if data is accessible and usable and move away from emphasizing counting and thresholds. **In order to effectively achieve this, CMS should collaborate with national specialty societies when they work to re-envision this program and beyond. This collaboration must include the development of health IT-enabled alternatives or pilots that could be optionally used to satisfy the ACI component of the composite score and new measures that are appropriate and meaningful.**

a. Patient Electronic Access to Health Information

The ACC strongly supports the right of patients to have access to their health information in a timely fashion and understands the importance of ensuring that patients understand their diagnoses and conditions. However, the finalized time requirements here are unreasonable. It is essential that an EP have the opportunity to review, correct and verify the accuracy of the information in order to prevent further harm to the patient. Instead, a more reasonable time requirement must be imposed to allow for this work to occur. CMS finalized requiring physicians to provide patients access to their health information within 48 hours of its availability for more than 80 percent of unique patients seen. The ACC contends that the 48-hour timeframe is inadequate since many who have adopted certified EHRs are now finding it necessary to spend more and more time after hours (typically one or two hours per day) just to try to keep up. There are numerous extenuating circumstances where a 48-hour turnaround might not be possible. Additionally, this further worsens the patient-clinician disconnect as more and more clinicians are using what should be face-to-face time to try to complete documentation work in the EHR. Instead, CMS should continue to rely upon the business day construct. The Stage 2 measure requires this information be furnished to patients within four business days. CMS provides no explanation as to why they finalized decreasing this requirement to 48 hours other than a patient’s right to access their information, a right which the College fully supports. As discussed during the development of Stages 1 and 2, there are many reasons for retaining a four business day requirement. **The ACC is concerned that the finalized 48-hour requirement may ultimately detract from the quality of care clinicians furnish patients, rather than the other way around as is intended. Thus, the College recommends that CMS retain the four-business day rule from Stage 2.**

Additionally, it is critical that the Agency consider the time commitment required from clinicians before electronic health information is made available to patients. Information must be viewed for accuracy and sensitivity. It would be poor care quality for a patient to learn of a potentially devastating diagnosis from a patient portal, personal health record (PHR), or any other form of health IT. While there is no “good” way to receive bad news, it is certainly more compassionate and better for the patient-clinician relationship that such information be conveyed directly and personally to the patient by the clinician. Thus, it is essential that time be allowed for clinician review and screening of information

before it is accessible to patients. Before this information exchange can occur in a meaningful way with patients, clinicians must be comfortable using EHRs and information exchanges to share information amongst themselves.

The ACC recognizes that there are some patients who may be interested in obtaining electronic access to their medical records. However, rather than focusing their resources on patient care and improvements to that care, the program as finalized will force physicians to shift those resources where they will not have the level of impact they would have if spent on direct patient care. Physicians will be unduly confined to their patients' interest in accessing their medical information online for this objective. Again, the finalized decrease in the patient wait time for the availability of information online from Stage 2's four business days to within 48 hours is too aggressive.

According to the Stage 3 preamble, "This objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access." Unfortunately, CMS refuses to accept the realities of the situation. As finalized, clinicians will be required to provide timely information to patients online. Clinicians cannot force patients to enroll in their online portal, and they are provided very few alternative options to transmit a patient's information electronically until the patient has enrolled in the portal. Those who already have portals have experienced difficulties enticing patients to enroll in them. Thus, what will occur is that organizations that can afford to do so will hire staff whose sole job will be to sit in the lobby or waiting room and sign patients into their electronic records. This allows clinicians to meet their 80 percent requirement, but it does not truly accomplish much toward the intended goal of this requirement: engagement of patients in their care. Clinicians and medical practices that cannot afford to do so will be left to the mercy of their patients' comfort with using technology to access their confidential and private medical records, something with which a large majority of patients are clearly still uncomfortable. Of course, if patients will not even enroll in the portal, the likelihood of them actually using it to access their information is even smaller.

There are those who are of the opinion that all patients need to access their information electronically for education. These same individuals believe that the education should be furnished by clinicians, so these measures are intended to be an incentive for clinicians to conduct that education. However, clinicians who have implemented patient portals report that patients typically do not take advantage of them, and those that do are generally not Medicare or Medicaid beneficiaries. In actuality, clinicians and office staff do not have the time required to provide patients with individualized, detailed information as to the reasons for them to do so, other than, of course, to allow clinicians to successfully meet the requirements of this program. Instead, clinicians and office staff should spend their time and resources on patient care and related tasks.

Requiring clinicians to educate their patients on patient portals and similar tools will reduce their available time for patient care, thereby reducing the quality, the exact opposite of the effect intended by the shift to EHRs. **The ACC opposes the program requirements that hold clinicians accountable for actions beyond their control, such as interest in signing up for the patient portal by patients.** Alternatively, this energy could be redirected to focus on improved patient compliance and accountability documentation which holds patients accountable for dietary and lifestyle choices that negatively impact health outcomes, instead of penalizing clinicians for factors that they cannot control despite patient counseling. Not only should clinicians not be held accountable for the actions of others, but patients should not be forced to use technology to access their medical information if they are uncomfortable with it simply because the government thinks they ought to access the information this way. In order to engage a broader audience, the ACC would suggest that CMS expand the opportunities to engage beyond the patient portal and view/download/transmit construct provided; leverage ONC's privacy toolkit to unlock data that was previously difficult to obtain due to unnavigable privacy laws and guidelines; and increase

the usability of patient engagement tools. **CMS must also recognize the costs – financial and otherwise – to physicians and hospitals as they adopt and implement EHRs when crafting the programs requirements.**

Members of the cardiovascular care team are fully committed to the provision of patient-centered care when it comes to factors which they can control. In order to fully participate in making decisions pertaining to their own care, patients must be sufficiently educated regarding their disease or condition and various treatment options. For this requirement to improve patient care, the patient-education resources must be relevant to the individual patient and the specialty of the treating clinician. General educational resources, such as information on the importance of annual flu shots, are less helpful and do little to educate patients regarding their own health. It is critical that the materials provided are at appropriate literacy and cultural competency levels for individual patients. **The College urges CMS to work with medical specialty societies such as the ACC and educational material vendors to identify materials appropriate for these purposes. The ACC is firmly committed to the provision of such materials to assist communications between patients and clinicians.**

In 2008, as a result of the ACC's commitment to patient-centered care and response to the lack of accurate, authoritative patient resources related to cardiovascular disease, the College launched CardioSmart.org, a patient-facing website providing educational materials on cardiovascular disease and associated conditions along with relevant therapies and treatment options. Cardiovascular specialists are encouraged to direct their patients to these resources, where they can also find mobile apps and online programs to help them live more fully with their condition. The CardioSmart.org website incorporates interactive information and tools to better engage patients in understanding their health and working with their cardiac care team. It is also the primary dissemination point for ACC's shared decision making tools, which offer evidence-based decision aids to help patients better understand their preferences for care in light of the risks and benefits associated with their care options. The ACC has also partnered with a number of patient advocacy organizations to expand its reach for content dissemination so that patients throughout the United States have more effective and higher quality conversations with their physicians and participate more actively in their care. In addition to the website, the CardioSmart brand also hosts a text messaging service for which patients can register to receive text messages with practical tips, advice and reminders to prevent heart disease and to stop smoking. The ACC has also developed a CardioSmart app, a virtual anatomical model of the heart, available for iPad users, to assist cardiovascular specialists in educating patients about their condition at the point of care. **A number of medical specialty societies have developed patient-facing websites and educational materials. The ACC urges CMS to work with medical specialty societies and EHR vendors to ensure that patients are receiving accurate educational materials pertaining to their individual needs and concerns.**

With respect to patient specific electronic educational resources, the ACC continues to believe that clinicians should have the flexibility to provide these resources in whatever is the most useful format for their patients (e.g., electronic copy, printed copy, electronic link to source materials, through a patient portal or personal health record). Currently, there are concerns regarding availability because EHRs may not include the full spectrum of educational materials, which leaves out tools that may be the best sources for patients. Also, the EHR may contain insufficient resources in foreign languages for patients who do not speak English or for whom English is their second language, only adding to existing health disparities based on language barriers. Third, the sub-par usability of EHRs leads to an increased focus on documenting a patient encounter rather than focus on the patient and interacting with them.

Cardiovascular specialists report that they have to hunt and peck for the information in the EHR, which takes longer than providing the patients a handout; what was once a one minute task has now expanded into a process that requires querying, searching, filtering, and printing. **Therefore, the College suggests that CMS not limit educational resources to those identified by Certified EHR Technology, but instead, to also consider other methods that may be more efficient and superior for providing this**

information. These revisions would allow patients to become more accustomed to using these tools themselves, so they are then more inclined to use them in the future for clinical purposes.

b. Coordination of Care through Patient Engagement

The ACI proposal clearly demonstrates CMS' continued interest in engaging patients and their families, a laudable goal. The ACC agrees that it is critical to involve patients and their families in care decisions. However, despite combining numerous Stage 2 core and menu objectives to create this objective, Stage 3, and thus the ACI proposal, continues to embody the complexities of the early stages of the EHR program. While it does appear that participants are provided flexibility when they have a few options within a measure, this only truly exists if the options actually exist in the market for which participants can leverage them in their healthcare setting. Additionally, the objective should recognize age and cultural gaps that could result in a digital divide if clinicians do not have explicit exceptions to ensure these patients can be included in the relevant measures. For example, the objective, which requires patients to actively engage with the electronic health record made accessible by the provider, should be expanded to include a broader set of actions, such as convenience tools (billing/appointment scheduling) to better meet patients' needs and increase the likelihood that clinicians will be able to meet this measure.

With respect to those eligible to send or receive secure messages, the term "care team" or "team member" is never defined within the final rule and is unclear as to whether this is limited only to clinicians enrolled in the Medicare program or if it extends to nurses and other clinical personnel. The College requests that the Agency provide clarification pertaining to this requirement in further rulemaking. Furthermore, clinicians cannot continue to be held responsible for their patients' decisions regarding preferred methods of communicating with them and office staff. Many of the secure messaging programs continue to be cumbersome to use, even for those patients who are technologically inclined. Therefore, the fact that the objective's rigidity has been eased through the inclusion of communications from the clinicians and relevant communications amongst the care team doesn't entirely alleviate the hurdle this overly ambitious objective provides. **The College continues to remind CMS that controlling clinicians through the actions of their patients is inappropriate and urges CMS to instead redirect this focus onto vendors so they can bring more effective options to market within a timeframe that provides for adequate improvements and testing so the product can fit the needs of a broader range of clinicians.**

The College is concerned that CMS would finalize the collection of patient generated data (PGD) as an option, despite the Agency's knowledge and participation in ongoing discussions regarding the lack of standardized data capture abilities for such data. Given the new emphasis the Agency has placed on interoperability and the collection of structured data, it is clear that implementation of this measure is premature. As such, the ACC opposes the inclusion of this measure among the ACI requirements.

c. Health Information Exchange (HIE)

For clinicians, the HIE objective introduces another element of uncertainty. They frequently conduct histories and physical examinations when a patient is hospitalized. However, this information may or may not be entered into their practice's EHR, making it difficult to track as a transition of care. Additionally, it is highly likely that their practice's EHR does not interface with the facility's EHR, so information between the two systems is unlikely to be shared. Patients are frequently sent to the emergency room outside of normal business hours, so clinicians may not know that their patients have experienced a transition of care, triggering the requirement that a summary of care record be provided. The rule finalizes the requirement that clinicians would need to actively seek, as a recipient of a transition or referral, an electronic summary of care document in a patient's record when a patient is referred to them or otherwise transferred to them for care. The health system's complexities and fragmentation makes it difficult to

track these transitions electronically for measurement purposes, in addition to the difficulties experienced when clinicians are required to actively seek the various records. Given the current definitions of transitions of care and referrals, clinicians will have a difficult time distinguishing when these records must be furnished. **Until industry solutions to these issues have reached an adequate level of adoption, CMS must revise this objective and the associated measures. Rather than focusing efforts on moving more data, the College strongly recommends that the focus remain on furthering functional interoperability, that is, the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.**

An additional component of this objective is that the clinician or hospital transitioning or referring their patient to another setting or clinician must electronically transmit a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different EHR vendor than the sender. **Given the state of interoperability and data blocking by non-clinicians, the ACC is extremely concerned about the ability of clinicians to meet this measure once, let alone multiple times, particularly in the absence of information on how performance will be scored. While the College understands CMS' intention to help drive the electronic exchange of information, this measure is outside the control of clinicians or hospitals.** Recent changes in reimbursement have led to resulting changes in the ownership structure of ambulatory practices. More and more private practices have been acquired by hospitals. This means that many clinicians are employed by integrated health systems or hospitals, have little to no control over the EHR they use, and may use the exact same EHR as virtually every other clinician with whom they typically interact. Given these changes, clinicians may not have the need or ability to electronically exchange data with clinicians using different EHRs.

Even where clinicians are not part of the same health system or employed by the same hospital, they may use the same EHR as the other clinicians in their geographic region or have no information regarding the EHRs used by clinicians with whom they frequently interact. Requiring clinicians to transmit summaries of care to recipients with no organizational affiliation and a different EHR requires clinicians and hospitals to perform activities over which they have no control or ability to track. **As such, the College opposes inclusion of this measure in the ACI component of MIPS. At a minimum, the ACC urges CMS to provide exclusions for clinicians and hospitals that do not transition care or refer patients to a minimum number of clinicians or hospitals with different organization affiliations and/or different EHRs.**

Given that this measure is more difficult to implement than it appears, most practices and hospitals are required to interface with more than one clinical laboratory. Physicians generally have privileges at multiple hospitals, and each has its own laboratory or requires the use of a particular laboratory. Additionally, health insurance companies have different requirements when it comes to the use of particular laboratories. Thus, the costs and ability of medical practices to develop interfaces with multiple labs are really out of their control. One lab interface alone can take six months to a year to implement, and practices and hospitals pay for each interface that they implement. The costs and resources needed to develop the multitude of interfaces necessary to accomplish this measure are beyond the proposed implementation timeline. Health information exchanges (HIEs) may assist medical practices and hospitals in meeting these requirements, but they either do not yet exist in many states or they may not be functioning at the levels necessary to remedy this situation. **Until industry solutions to these issues have reached an adequate level of adoption, CMS must revise this objective and associated measures to provide clinicians with at least a minimal opportunity to meet the requirements.**

d. Public health and clinical data registry reporting

The ACC is a strong supporter of registry reporting and critical data collection efforts. To that end, the College largely agrees with the Agency's proposal with respect to public health and clinical data registry reporting for 2017 and 2018.

Tracking immunizations is clearly important. That said, the College appreciates the proposal to continue the exclusion for reporting to an immunization registry where clinicians do not provide more than a minimal number of immunizations. Cardiovascular specialists frequently do not offer vaccinations and would be inappropriately penalized without this exclusion.

Reporting to clinical data registries remains challenging for some and could prevent success in the ACI performance category, given the technological barriers that remain, such as the lack of interoperability. Additionally, mandating participation could cause an unprecedented surge in registry enrollment, which, on the surface, seems like a good problem to have. However, the time it takes to move through the steps necessary for achieving active engagement, is not insubstantial. In fact, it can take many months to finalize agreements, map out the relevant data elements, test the mapping and move into production. Clinical data registries will also need time to adapt to this influx. Given these concerns, the College supports not mandating clinical data registry reporting at this time. That said, the ACC also agrees that those clinicians reporting data to clinical data registries should be rewarded for such activities. Providing them the option of earning bonus points under the ACI category would appear to be an appropriate mechanism for doing so.

While the College supports population and public health activities, the ACC believe expanding the ACI requirements to include reporting to public health registries, for syndromic surveillance, or of electronic cases would be premature. As such, the College supports the use of the bonus concept for rewarding those who are able to participate but not penalizing those who are not, regardless of the reason.

Hardships

The College continues to advocate for reduced performance periods for new clinicians and for years with substantial programmatic changes. That said, if CMS does not finalize a reduced reporting period for these circumstances, the ACC encourages CMS to consider the creation of a hardship category for individuals in such circumstances. While clinicians are not subject to MIPS until a year enrolled in the Medicare program, there is so much for new clinicians to learn about the practice of medicine that it would be unfair to also place on them the burden of learning a new EHR and requirements for its use. As such, the College urges CMS to provide additional flexibility under the ACI component of MIPS for new clinicians. Additionally, substantial programmatic changes to the ACI component of MIPS will require substantial education of clinicians and staff, as well as time and resources for implementation. In some cases, it may require migration to entirely new certified EHR technology, which will also require time and resources for education and implementation above and beyond those required for the programmatic changes. **To ensure that clinicians and medical practices have the appropriate amount of time to adjust, the ACC supports the creation of a hardship category for years when significant programmatic changes are to be implemented, such as the new edition of health IT certification regulations, substantial changes to the ACI objectives and measures and other similar situations.**

In the proposed rule, CMS does allow for the possibility of extreme and uncontrollable circumstances requiring latitude for clinicians. **Given the importance of certified EHR technology to the ability of clinicians to successfully participate in the ACI component of MIPS, the College urges the Agency to consider the de-certification of an EHR an extreme or uncontrollable circumstance requiring**

such forbearance. The lack of control on the part of the clinician or medical practice in such circumstances should absolve them of fault. **Additionally, the ACC reminds CMS of the lengthy timeline required for the purchase, installation and implementation of a new EHR that is appropriate for a particular medical practice and urges CMS to include these as factors when considering for how long latitude is granted.**

Advanced practice professionals (APPs)

The College strongly supports team-based care. According to the ACC’s Health Policy Statement on Cardiovascular Team-Based Care and the Role of Advanced Practice Providers, “Cardiovascular team-based care is a paradigm for practice that can transform care, improve heart health, and help meet the demands of the future.”¹ Shared goals are key to the success of team-based care. As such, all members of the team should be incentivized to implement and use health IT to improve the quality of patient care. Assuming there are sufficient applicable measures, the College supports the inclusion of APPs in the ACI component of MIPS.

That said, the College does have one concern with respect to measurement of APP use of health IT. Addressing attribution in medicine has long been problematic, regardless of what is being measured, and has contributed to the delay in the development and implementation of outcomes measures. The College believes that attribution will create problems when measuring an APP’s use of health IT, as well. Under Medicare billing rules, APPs may at times bill for their services under their own National Provider Identifier (NPI) and at other times “incident to” another clinician’s services. Because of this, it may be difficult to measure whether an APP is in fact meaningfully using health IT to its fullest extent. **The College urges CMS to ensure that APPs are appropriately recognized for their use of health IT.**

Medicaid

While the College understands that MACRA only applied to the Medicare program, the ACC believes that the Agency has the statutory authority under HITECH to ensure alignment in its quality programs. As such, the College urges CMS to take the requisite steps to eliminate duplicative and administratively burdensome reporting requirements. This applies not only to Medicare programs, but to the Medicaid program, as well. For clinicians treating both Medicare and Medicaid programs, separate reporting programs creates the potential for a situation where a clinician has met all of the requirements but mistakenly fails to report to one, leaving them facing a payment adjustment of some kind, whether it is not meeting the full requirements for the ACI component of MIPS or not earning the Medicaid EHR Program incentive.

MIPS APMs

APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

The ACC appreciates CMS’ proposals to provide MIPS incentives to 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 and 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.

¹ 2015 ACC Health Policy Statement on Cardiovascular Team-Based Care and the Role of Advanced Practice Providers. *J Am Coll Cardiol.* 2015; 65(19):2129.

APM Participant Identifier and Participant Database

CMS proposes the development of an APM participant database identifying each APM identifier, APM Entity identifier, eligible clinician billing TINs, and eligible clinician NPI numbers. The ACC supports the use of this database to communicate to each APM entity the MIPS eligible clinicians included under that entity during the MIPS performance period. It is important that APM entities have this resource to verify those clinicians who may be subject to different MIPS reporting requirements based on their participation in an APM. In future years, as “other payer” APM entities are incorporated into the program, CMS should ensure that this resource also links to the payers managing recognized models.

CMS recognizes that there will be eligible clinicians who may change TINs and this may affect their APM status during a given year. The ACC supports creating a defined threshold to consider a MIPS eligible clinician as part of a MIPS APM if he or she is participating in an APM entity on December 31 of a given performance period. This defined threshold will make it easier for APM entities and clinicians to understand their status. Throughout the performance period, clinicians and APM entities should receive updates from CMS as to whether or not an eligible clinician is affiliated with a MIPS APM. The ACC recognizes that in order for CMS to provide this feedback, APM entities and practices will need to update their clinician NPI records on an ongoing basis.

CMS proposes to calculate a single MIPS CPS for each APM entity group and apply it to all clinicians in the group. **As stated previously, the ACC strongly encourages CMS to consider ways to factor individual specialty MIPS composite performance into the calculation of any group score under MIPS or a MIPS APM.** As proposed, there are no specialty-focused APMs proposed as MIPS APMs. It will be difficult for cardiologists and cardiology team members to demonstrate contributions to improvements in the quality and value of patient care. As a result, these clinicians are scored based on the performance of their colleagues and potentially care that they are not directly responsible for. In order for MIPS APM scoring to be clinically relevant to each clinician in the model, CMS must implement specialty-focused MIPS APMs and seek ways that all clinicians under a model can report the most clinically relevant MIPS data.

APM Entity Definition

The proposed rule defines an APM entity as an entity that participates in an APM or Other Payer APM through a direct agreement with CMS or a non-Medicare payer respectively. However, specifying “direct” agreement renders this definition too narrow. **The definition of APM entity should be expanded to include both those entities that have a “direct agreement” with CMS or a non-Medicare payer, as well as those entities that have a participation agreement with CMS through another entity, such as a convener organization.** This would allow models such as Bundled Payments for Care Improvement (BPCI) meet the APM entity definition.

APM Entity Group Scoring for the MIPS Performance Categories

The ACC supports CMS’ intent to avoid duplicative data reporting by not assessing a MIPS eligible clinician in categories that are already being assessed under the APM entity; however, we have concerns about how the proposed policies would impact clinicians.

The ACC supports redistribution of the resource use weight for clinicians participating in the Medicare Shared Savings Program (Track 1) or the Next Generation ACO Model to the quality and CPIA sections of the MIPS CPS, as these programs have their own methodologies for calculating resource use. **However, the College has serious concerns about the scoring weights proposed for MIPS APMs other than these two models, especially as any new MIPS APMs will likely be subject to the “all**

other MIPS APMs” threshold. For all other MIPS APMs, CMS proposes to weight the MIPS score at 25% CPIA and 75% ACI. Given concerns about ACI scoring as proposed, and the historical difficulty that many clinicians and groups have faced in meeting the EHR Incentive Program requirements, we oppose the application of such a high weight assigned to the ACI category, especially as EHR use may not be the core focus of several models.

CMS states that there are operational challenges to measuring quality for these other MIPS APMs during the first performance year, as there is insufficient time to align quality measures reported by models under this category and the reporting and scoring requirements proposed for MIPS. While the College supports CMS’ consideration of efficiency and alignment in quality reporting, the ACC is concerned that this proposed scoring does not recognize clinicians for their efforts to improve the quality of care, which should be the foremost priority of any MIPS APM. **The College understands that in order to have a CPS, at least two MIPS categories must be reported. Therefore, the ACC recommends that CMS reweight the proposed scoring for MIPS APMs other than MSSP Track 1 or the Next Generation ACO to 75% CPIA and 25% ACI. This will ensure that clinicians are rewarded for participation in activities that contribute to quality improvement, rather than “clicking boxes,” until alignment of quality measures can be developed for future years of the program.**

MIPS Composite Performance Score

The ACC strongly supports CMS’ vision to create a MIPS scoring methodology that allows for accountability and alignment, and that is meaningful, understandable, and flexible for all MIPS eligible clinicians. In order for MIPS to be truly impactful to clinician performance, simplified scoring must also be accompanied by a mechanism for providing clinicians and groups with straightforward feedback that allows them to clearly understand their performance without the burden of deciphering lengthy reports and methodology.

Quality Measure Benchmarks

The ACC supports the proposal to create separate benchmarks based on the data submission option (i.e., EHR, qualified registry, QCDR, claims). Not only will this proposal eliminate issues of different measure specifications being used in EHR reporting versus registry, but it will also support the use of QCDRs as an efficient mechanism for providing clinician feedback as the benchmarks applicable to the QCDR will be used for MIPS scoring.

Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria

CMS proposes to move away from “all or nothing scoring” under the quality composite by awarding points for any reported measures that meet the required case minimum. A clinician would receive a zero score for any required measures not reported, not the entire quality category. **The ACC supports this approach, which moves away from the current PQRS automatic penalty for failing to meet the required number of measures, with no credit awarded for measures actually reported.**

Incentives to Use CEHRT to Support Quality Performance Category Submissions

The ACC supports bonus points for “end-to-end electronic reporting” of quality measures using certified EHR technology (CEHRT). However, structured reporting is still a goal that the NCDR and other EHR and registry vendors are trying to achieve. Many clinicians will be unable to achieve these points in the initial years of the MIPS program until proper infrastructure is in place. In addition to the bonus points, CMS and ONC should continue to work with vendors to develop standards that would support this approach to reporting quality data.

Risk Adjustment

The ACC strongly supports the application of risk adjustment to the resource use and quality measures, particularly outcome measures, used in the MIPS CPS. MIPS cannot and should not be a system that unintentionally penalizes clinicians for treating high-risk patient populations. Several quality measure developers such as the ACC/AHA incorporate risk adjustment in their methodologies through measure exceptions and exclusions. In addition to improving risk adjustment, CMS should also consider risk stratification rather than adjustment for elements such as socioeconomic status. The ACC looks forward to future work by CMS and measure stakeholders to develop more robust risk adjustment and stratification methodologies for measuring cost and quality of care.

MIPS Payment Adjustments

CPS Used in Payment Adjustment Calculation

CMS proposes to apply the MIPS composite performance score (CPS) at the TIN/NPI level, regardless of whether clinicians report as a group, individual, or APM entity. The ACC supports this approach, as well as the proposal to have a clinician’s historical MIPS CPS used for payment if he or she changes practices, until he or she is able to establish a new CPS under the new TIN. The College agrees with CMS that this approach ensures that MIPS eligible clinicians are accountable for their performance. However, if performance is to track individual clinicians, all clinicians, even those reporting at the group level, must be able to report and be scored against measures that align with the care that they provide.

For clinicians who bill under more than one TIN during the performance period, CMS proposes to apply a weighted average of all submitted MIPS scores or to apply only the highest score affiliated with a TIN/NPI combination. **The ACC supports the latter approach to use the highest TIN score in instances where a clinician has multiple MIPS scores.** The College appreciates the proposals by CMS to clarify the policy around clinicians reporting under multiple TINs, as this is common among cardiologists and has created a lot of confusion under the current Medicare quality reporting programs.

Performance Feedback

CMS proposes to begin providing performance feedback starting on July 1, 2017. In this initial feedback report, CMS should be clear that in the absence of historical MIPS data in the first performance year, feedback is based on CY 2015 and CY 2016 data under the current quality reporting programs. This will help clinicians identify potential areas of disconnect in their data in comparing past program performance to the new MIPS requirements. As historical performance under PQRS, the Value Modifier, and the EHR Incentive will be a predictor of first-year performance under MIPS, the ACC strongly recommends that CMS begin implementing any improvements to provide performance feedback on the current reporting programs now so that clinicians have this information early and can use it to prepare for MIPS.

While the ACC recognizes that some stakeholders find the current Quality and Resource Use Reports (QRURs) useful, for many clinicians these reports are complex and difficult to understand if they can even obtain the reports. In addition to providing this detailed data, CMS should continue to work with stakeholders to develop a report format that is clear, accessible, and actionable. This is especially important as scoring on episode groups becomes more prominent under MIPS. **The ACC strongly recommends improvements to the content and accessibility of supplemental QRURs to encourage familiarity with cost performance data and the clinical episodes that will be attributed to a clinician or group.**

Under the current proposal, CMS proposes to limit the requirement to furnish clinicians with feedback reports to the quality and resource use performance categories. The ACC believes that this requirement should be extended to include the ACI component of the program, as well. While the statute may not require such reporting to MIPS eligible clinicians, the College believes that it is important for clinicians to receive ongoing information regarding their performance with respect to their use of health IT. The feedback should be provided on a quarterly basis, so clinicians can avail themselves of the opportunity to improve their performance in a timely manner, rather than having to wait until the following year. **To that end, the College urges CMS to adopt a requirement that clinicians be furnished quarterly feedback on their ACI performance during the reporting period.** CMS should also continue to evaluate and work with vendors to determine how EHR systems and QCDRs can be leveraged to provide more ongoing performance feedback to clinicians.

Targeted Review

The ACC strongly supports the inclusion of an informal review process for MIPS eligible clinicians and groups who believe that CMS has assigned an incorrect CPS or penalty. The current Medicare quality reporting programs include a similar informal review process; based on the experience of the College's members with this process, the ACC makes the following recommendation to improve informal review under MIPS.

First, the communication notifying clinicians and practices of their penalties under PQRS (“An Important Message from the Centers for Medicare & Medicaid Services About the Physician Quality Reporting System”) has been vague and needs to be customized to each clinician and group. The notification states that PQRS reporting criteria have not been met, but it does not provide clinicians or practices with clear information as to why exactly they failed to meet criteria. As a result, many practices have had to spend time seeking this information through the QualityNet Help Desk, which takes away from the time they could be using to evaluate their data and determine whether or not they may have a successful case for informal review. Any notification informing clinicians or groups of a penalty or low CPS under MIPS should be accompanied with the exact reason, such as failure to report sufficient number of measures or low benchmark performance. Providing this information will not only help practices and clinicians with their immediate informal review requests, but also assist them with learning the MIPS requirements and what they need to do to improve their reporting or performance. CMS should include warning notices during the feedback provided during the performance year to notify clinicians and groups of potential missing requirements so that steps can be taken to fill these gaps before the close of the year.

Second, the College has serious concerns with the proposal to “reopen, revise, and recoup any resulting overpayments” if a clinician is found to have submitted inaccurate data for MIPS. Based on experience with PQRS, the College is aware of many practices and clinicians who have unintentionally submitted data deemed inaccurate by CMS or its contractors due to misunderstanding of the PQRS reporting requirements, or due to differences in documentation in the clinicians’ notes. Given the complexity of the MIPS regulations as proposed, there will likely be many clinicians and practices submitting inaccurate data in the initial years of the programs, especially as some clinicians become familiar with new measures and attribution methodologies under MIPS. Any proposal to “reopen, revise, and recoup” overpayments should be narrowly limited to clinicians and groups where there is apparent fraudulent activity.

Third, CMS and its contractors should coordinate reporting vendors when contacting practices for information under a targeted review. At a minimum, CMS and its contractors should share a copy of the notification sent to clinicians and practices with the EHR vendor, qualified registry, or QCDR responsible for reporting that clinician’s or group’s data. In the past year, several practices contacted the ACC’s PINNACLE and Diabetes Collaborative Registry requesting assistance in pulling data for the

audit. If the vendors are aware of the audit request, staff can be better prepared to assist practices in pulling required data so practices can comply with the audit in a timely manner. The ACC also received many questions from practices that were unclear whether the audit was mandatory or voluntary. Having the notification can help vendor customer support staff answer these questions. At the conclusion of the audit, vendors should receive the result of the review, in addition to the practice. This will help vendors determine if data issues potentially lie with the vendor, or if the vendor should better support the practice in reporting data more accurately.

Finally, CMS must continue to allow clinicians and groups to submit information for informal review without the fear of an additional penalty by CMS or its contractors. The ACC supports the current policy which does not impose an additional penalty on clinicians or groups who submit an informal review that is found to result in no changes to CMS' original determination.

Qualified Clinical Data Registry (QCDR) Data Submission

Third Party Data Submission

As previously stated, the ACC supports the proposal to recognize QCDRs as a reporting mechanism for data submission across three categories of MIPS – quality, ACI, and CPIA. The ACC currently submits PQRS data on behalf of clinicians and group practices via the NCDR PINNACLE and Diabetes Collaborative QCDRs and intends to utilize these registries and others as well. **As MIPS regulations continue to be updated annually, the ACC recommends that CMS and its contractors work with vendors to ensure that any proposed changes are not burdensome and do not limit the adoption of QCDRs as a quality improvement tool and reporting mechanism for clinicians and practices.**

The ACC agrees that data accuracy is of utmost importance under a performance-based payment system such as MIPS. **The College supports the proposal stating that data inaccuracies affecting in excess of three percent of the total number of MIPS eligible clinicians submitted by the QCDR result in a posting of low quality on the QCDR's listing and a probationary period. However, "data inaccuracies" should be based solely on calculation errors performed by the QCDR.** QCDRs should not be penalized for errors that may result from submitting clinicians and groups such as the submission of data on behalf of a clinician who does not need to report quality data (e.g., Advanced APM qualifying participant) when the QCDR is unaware that the clinician is part of a model, as well as TIN/NPI errors, formatting issues, and documentation notes that are outside of the QCDR's control. Prior to any probationary period or public posting of low quality reporting, CMS and its contractors must communicate directly with the QCDR and provide the QCDR with an opportunity to address any errors or discrepancies.

QCDR Quality Measures

The ACC continues to support QCDRs as a mechanism for the efficient implementation of quality measures. **CMS should allow measures stewards to modify MIPS measures and report them as non-MIPS measures through QCDRs. The current Measures Under Consideration (MUC) process is not flexible enough to update measures in a timely manner to ensure that the most clinically appropriate measures are being utilized.**

CMS proposes that "a measure that may be in the annual list of MIPS quality measures but has substantive differences in the manner it is submitted by the QCDR" will be considered a non-MIPS quality measure. **The College requests that CMS clarify what a "substantive difference" means.** The ACC has submitted several quality measures for approval as non-PQRS measures reported through a QCDR. To date, three measures have been rejected for approval as non-PQRS measures because they

were deemed too similar to PQRS measures. These measures are all clinically important to cardiovascular care and the College believed that they were different enough from the PQRS versions that they could be submitted as non-PQRS measures. It remains unclear specifically what aspects of the QCDR version of a quality measure need to be different in order to be approved as a non-PQRS/non-MIPS measure.

The College recommends that clinicians and groups reporting non-MIPS measures that fall into one of the high-priority categories (outcome/intermediate outcome, appropriate use, patient safety, efficiency, patient experience, care coordination) receive bonus points under the quality category. It is unclear from the proposed rule whether the bonus points would only apply to MIPS measures.

Lastly, CMS should continue to work with QCDR vendors to determine the best timelines for data submission and self-nomination. Under the current PQRS process, the 2015 data submission dates, 2016 self-nomination period, and 2014 data audit processes overlap. In addition to these three processes, QCDR staff are working diligently to assist practices in reviewing their data, learn new program requirements for the upcoming year, and update systems and education. CMS and its contractors should determine whether it is feasible to decouple these processes. At a minimum, the ACC recommends that CMS decouple the measure selection and approval process from self-nomination and stagger the dates for these windows. This will allow QCDRs more time to dedicate to measure selection and allow them to work with CMS and its contractors, resolve any issues related to approval of measures, and have time to educate clinicians and groups on new measure specifications as soon as the performance year begins.

Public Reporting on Physician Compare

Before public reporting information pertaining to the MIPS program, the College urges CMS to ensure that the information being publicly reported is useful and understandable for patients. The measures reported must be statistically validated and tested as is required for all other types of measures. Additionally, the College recommends the Agency consult with consumer and patient stakeholder representatives to verify usability, as well as with health literacy experts to ensure the measures and information are presented in such a way as to present patients with information that is useful.

The College recommends that CMS delay public reporting on the MIPS program components for at least two years, that is, until clinicians have been afforded the opportunity to review their feedback and adjust their performance accordingly under the new payment system. Publicly reporting information based on data from the first two years of the program would be premature and could potentially provide patients with a false impression of the quality of care furnished. The data provided on Physician Compare also needs to be clarified to identify individual level versus group level reporting, and how beneficiaries should understand the information based on this distinction. It is essential that patients are provided accurate information regarding their care.

Advanced Alternative Payment Models

MACRA establishes the Advanced Alternative Payment Model (Advanced APM) pathway to reward clinicians for participation in models that accelerate the transition from volume to value. **The ACC supports incentives for participation in advanced APMs, but is disappointed to see that the proposed list of Advanced APMs for 2017 is narrow and provides little to no opportunity for specialists to participate or be impactful under this pathway.** The College recognizes that CMS may be limited by the definition of Advanced APMs as written in the MACRA legislation; however, one of CMS' stated goals is to "create policies that allow for flexibility in future innovative advanced APMs." The College strongly encourages CMS to exercise this flexibility as it updates the advanced APM list in future years and also look to the guidance of the Physician-Focused Payment Model Technical Advisory

Committee (PTAC) to determine how to support the adoption of specialty and clinician-focused payment models.

MACRA was crafted in a way that presents clinicians with a “choice” of participating in MIPS or an Advanced APM. Upon reading the proposed rule, it appears that the ability for a clinician to choose a pathway is limited. The initial list of Advanced APMs reflects models that only larger institutions and health systems will be able to implement with success. Small and private practice clinicians will likely be shut out of this pathway unless they integrate with one of these systems. CMS should broaden the scope of models available under the Advanced APM pathway so that integration is not the only way for these clinicians to participate in the transformation of care.

In determining which APMs are classified as advanced APMs, a key area to focus attention on is care adequacy. CMS should determine that each Advanced APM has robust evidence-based measures that promote care adequacy to ensure that there is care is not being shortchanged in effort to reduce costs. Ignoring the care adequacy issue should be unacceptable.

The College is aware that CMS and the Center for Medicare and Medicaid Innovation (CMMI) remain interested in implementing mandatory payment models for services and patient populations such as the Comprehensive Care for Joint Replacement (CJR) Model. **If CMS and CMMI are to expand the scope of mandatory payment models to encompass other conditions and procedures, the ACC recommends that such models be designed to fit Advanced APM criteria and that participation in these models be recognized as participation in an Advanced APM. Any model must first be piloted and refined based on the results of the pilot before widespread or mandatory implementation.**

Advanced APM Determination

Many specialists are involved in bundled payment programs, such as the Bundled Payments for Care Improvement Initiative (BPCI). While BPCI meets the proposed financial risk standard, it does not meet CEHRT and quality measure requirements. The College supports recognition of BPCI as an Advanced APM, or at least as a MIPS APM under the recommended scoring discussed previously (75% CPIA/25% ACI). One option for CMS to consider is to allow the amendment of BPCI contracts to meet either or both of these requirements. In doing so, BPCI participants could qualify as participating in either a MIPS APM or Advanced APM. **CMS should consider allowing BPCI contracts to be amended, based on participant readiness, to meet either the CEHRT or quality requirements or both to allow APM entities the option of qualifying as either a MIPS APM or Advanced APM.** BPCI represents a major opportunity for cardiologists and other specialists to qualify as participating in a MIPS APM or Advanced APM.

Qualifying Participant and Partial Qualifying Participant Status

CMS must provide clear feedback to clinicians to inform them of their status as a qualifying participant (QP) or partial QP in an advanced APM. This feedback should include information on the percentage of the clinician’s patients in an advanced APM as well as their revenue percentage through the advanced APM as of the date of the report. As CMS notes in the proposed rule, QP status depends on a variety of factors such as the specific APM pathway an entity is participating in (e.g., Medicare Shared Savings Program Track 1 versus Tracks 2 or 3), the payment amount threshold or patient amount threshold, and the QP’s status with the entity as of December 31 of each performance year. The College is aware of many clinicians who do not know that they are part of an APM by nature of being part of a health system. There will likely be many clinicians and groups that will not know whether or not they are QPs under the Advanced APM track. The ACC is concerned that these clinicians and groups may focus on their APM requirements and disregard MIPS, or vice versa, assuming that they are

participating in one pathway or the other. By the time they realize their status, it may be too late to catch up with requirements for their applicable program. CMS feedback directly to clinicians and practices regarding their QP status must be provided.

For partial QPs, CMS offers the option for these clinicians to elect whether to participate in MIPS or only participate in the requirements of their advanced APM. CMS should provide these clinicians with written notification of their partial QP status and provide them with as much MIPS feedback data as possible to allow them to make an informed decision about whether or not to participate in MIPS.

Patient Attribution

The ACC supports the proposal to base QP thresholds on either a percentage of payments received through an advanced APM or a percentage of patients treated who are attributed to an advanced APM. The patient threshold will make it easier for clinicians participating in specialty or disease-focused APMs to attain QP status, as patients under these models are typically a subset of a larger population, making it difficult to achieve the payment threshold. The ACC advocates for greater flexibility for specialty-specific APMs through regulatory waivers and other mechanisms that promote adoption of new models.

Advanced APMs and Health IT

CMS proposes to limit its requirements for health IT implementation and use by advanced APMs to ensuring that such entities use certified EHR technology. The College supports this hands-off approach as a way of allowing advanced APMs to use health IT in a manner that most appropriately addresses its needs. Such latitude will also afford advanced APMs to expand their innovations throughout their processes. **The ACC believes that MIPS eligible clinicians should be provided with similar opportunities to avoid the checkbox approach that has been promulgated through the EHR Incentive Program.**

Financial Risk

MACRA requires that advanced APMs assume “more than nominal financial risk.” Based on the definition proposed by CMS, this definition of risk encompasses different forms of financial risk, including total risk, marginal risk, and minimum loss rate calculations. **The ACC is concerned that the definition of “more than nominal financial risk” is overly complex and will make it difficult for clinicians to understand exactly what is at stake when they participate in one of these advanced APMs. CMS must develop clearer education that helps clinicians understand what is at stake when they participate in advanced APMs.**

The definition of “financial risk” should encompass those factors within the clinicians’ control. This includes payments for professional and technical services provided under Medicare Part B. When appropriate, entities should have the option to include hospital costs within their assumed risk. Financial risk should also include costs to the clinician outside of direct compensation such as the cost of hiring care coordinators, implementing clinical decision support, and contracting with experts to assist with data analysis. In order to implement advanced APMs at the clinician level, a heavy initial financial investment will be required and should be calculated into the financial risk threshold.

Physician-Focused Payment Models

MACRA introduces the concept of Physician-Focused Payment Models (PFPMs). **The ACC strongly encourages HHS to implement the work of the PTAC in reviewing and recommending PFPMs for**

CMMI consideration. It should be required that any model recommended by the PTAC be further developed and tested by CMMI with input from the model designer and affected stakeholder groups. To date, most payment models have focused on system-level changes that focus on institutional, rather than physician-level changes in practice. As the clinicians are the drivers of care delivery, any attempts to improve value and quality under the Medicare Part B program must focus on the care and services that are within the clinician's control.

To qualify as a PFPM, CMS states that models must meet criteria in the following three categories: (1) provide payment incentives for value over volume, (2) promote care delivery improvements, and (3) utilize information enhancements such as health IT to inform care. The College supports the required criteria; however, as previously stated in response to the ACI section of MIPS, interoperability is critical to many of the information enhancements that can be accomplished through the use of health IT. CMS should further expand the section on utilizing information enhancements such as health IT to inform care. CMS and ONC must insist that vendors facilitate the exchange of meaningful data into structured data fields.

Another key component to the success of PFPMs will be patient engagement. In further defining patient engagement activities within models, CMS must not measure clinicians against whether or not the patient understands whether he or she is in an APM; rather, clinicians should be measured and paid based on new and innovative ways to engage patients in practices such as improved understanding of their conditions and treatments. Under the PFPM pathway, CMS should place great emphasis on the recognizing the care delivery improvements that will contribute to cost savings. The ACC looks forward to working with PTAC, CMS, CMMI, and other stakeholders to explore innovative PFPMs that impact the delivery of cardiovascular care.

Finally, prior to the implementation of any PFPM or any MIPS or Advanced APM, CMS should be transparent with the model design and provide the public with the opportunity to review and provide comments on the model with ample time built in for preparation and implementation. Any model selected for implementation should first be run as a pilot and refined based on findings from the pilot before it is expanded to a national or mandatory program.

Conclusion

The Quality Payment Program under MACRA aligns with the ACC's own strategic vision to transform the delivery of care and encourage clinicians to provide high-quality patient care. The College is working diligently to understand the new requirements of the MIPS and Advanced APM pathways so that our membership can be prepared for the changes and understand their responsibilities under the new payment system. The College cannot emphasize enough how important it will be that CMS provide transparent education to clinicians and practice administrators to minimize the potential burden of these new policies. The ACC and other medical specialty societies are eager to assist the Agency in outreach efforts. As stated at the beginning of this letter, the ACC recognizes that there is a short period for clinicians and groups to prepare for the coming changes between the publication of the final rule and the start date of the program on January 1, 2017.

CMS should communicate closely with medical societies and practicing clinicians to catch any unintended consequences of the policies implemented under this program and to work together to determine solutions for improving the program as efficiently as possible. CMS should monitor implementation and take immediate action if a large number of clinicians and groups report difficulties with the program's requirements or if CMS sees discrepancies or high rates of low compliance or performance when the Agency pulls data for the initial feedback reports of the QPP. If this were to occur,

the College would support policies that hold all clinicians harmless until areas for program refinement can be identified and remedied through future rulemaking.

Thank you for your consideration of the ACC's comments to this proposed rule. Should you have any questions about the College's comments or request additional information, please contact Christine Perez, Associate Director of Medicare Payment & Quality Policy, at cperez@acc.org or (202) 375-6630.

Sincerely,

A handwritten signature in black ink that reads "Richard A. Chazal, MD, FACC". The signature is written in a cursive, flowing style.

Richard A. Chazal, MD, FACC
President