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September 30, 2016

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

RE: Medicare Program: Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) [CMS-5519-P]

Dear Acting Administrator Slavitt:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Medicare Program: Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) [CMS-5519-P] proposed rule as published in the Federal Register on August 2, 2016.

The American College of Cardiology (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 College shares the goals of improving quality of care and lowering costs for Medicare beneficiaries. In this regard, value-based payment models have significant potential to enhance patient care. The College acknowledges and appreciates efforts of the Centers for Medicare & Medicaid Services (CMS) in the

proposed rule to create pathways to reward specialists for delivering quality care through value-based payment models. The ACC, however, recognizes the extremely challenging nature of creating value-based payment models for patients with cardiovascular disease. We strongly urge CMS to proceed with great caution in implementing and testing such models. While we believe value-based payment models can be effective, particularly in encouraging improved collaboration, coordination of services and appropriate care transitions, we recognize that such models are only as strong as their clinical and operational design. Models such as the proposed episode payment models must allow for accurate beneficiary attribution, valid quality and cost measurement, meaningful comparisons, and ultimately development of best practices to achieve better health outcomes for patients. These overarching concepts frame the discussion throughout this comment letter.

The College has organized its comments into two sections, Episode Payment Models (EPMs) and the Cardiac Rehabilitation (CR) Incentive Payment Model.

EPISODE PAYMENT MODELS

Throughout this section, our comments reflect the following *themes*:

- CMS must **proceed with caution to avoid unintended consequences** of the proposed acute myocardial infarction (AMI) and coronary artery bypass graft (CABG) models. Additionally, CMS must **work with clinicians including cardiologists and the entire cardiovascular care team as well as administrators** to continue to **develop and refine the models.**

- An important distinction between medical diagnoses and procedural based episode of care models is that **medical diagnoses models** tend to **involve a patient population of greater complexity, often with life threatening conditions**. Where appropriate, this awareness should be reflected in the design of EPMs.

- As the proposed AMI model represents CMS' first undertaking in combining both medical management and procedure-based care through a mandatory bundle, it is crucial CMS work with the clinician community to **establish clinical homogeneity, limiting ambiguity as much as possible.** Limiting inclusion to the **most clinically similar subset of patients** allows for **meaningful comparisons** and ultimately **provides CMS the opportunity to *clearly* evaluate the impact of the EPMs on patient care and outcomes.**

- The ACC urges CMS to establish **meaningful quality measurement methodology** that **reflects an awareness of** the **inherent clinical complexities existing within the cardiovascular disease patient population**. The ACC supports use of existing resources most meaningful to the clinician community to gather and report data such as the National Cardiovascular Data Registry (NCDR®) as well as the cardiovascular measure set from the Core Quality Measure Collaborative released in February 2016 and included within the cardiovascular specialty measure set in the Medicare Access and CHIP Reauthorization Act (MACRA) proposed rule.

- CMS should **provide informational resources to support care coordination** both prior to and following discharge from the hospital. ACC has gained experience and insight into care coordination through our *Patient Navigator* and *Surviving AMI (SAMI)* programs. There is significant **opportunity for CMS to work with ACC to make informational resources available to assist clinicians with care coordination efforts**.

- The College is aware that **some hospitals have less experience with bundled payment, including** certain **rural hospitals.** Hospital capabilities and readiness must be closely monitored in the geographic areas selected for this pilot.

- **Although the College recognizes that by statute qualified Alternative Payment Model (APM) participant (QP) thresholds will be set in the MACRA final rule, the ACC remains concerned that these thresholds are unreasonably high.** These thresholds must be lowered if CMS desires to provide realistic opportunities for effective clinician participation in Advanced APMs.

- In situations where inpatient transfers between hospitals occur, the ACC urges CMS to **attribute patients in the AMI model to the hospital where revascularization procedures occur**. In particular, smaller hospitals may have limited choice as to where to refer AMI patients. Safeguards should be put in place to protect such hospitals.

- **Risk sharing must be meaningful to truly align incentives.** Clinicians' contributions in proportion to the total care provided to patients in the AMI model must be appropriately accounted for in risk sharing arrangements.

ACC's comments on episode payment models are arranged into the following key topic comment areas: **clinical homogeneity in the AMI model, AMI model quality measures, Advanced APMs, special policies for hospital transfers of beneficiaries with AMI, risk sharing and financial arrangements under EPMs and additional care coordination considerations**.

The proposed acute myocardial infarction (AMI) model is unique in that it represents a marked change from previous efforts of CMS. It will be the first episode payment model introduced by CMS to combine both medical management *and* procedure-based care. **Moreover, the majority of patients in the proposed AMI model, unlike those in the mandatory Comprehensive Care for Joint Replacement bundle, are likely to be facing a life threatening emergency. The potential for patient harm and serious unintended consequences is high**. **Therefore, ACC's comments direct particular attention on the AMI model. The College encourages CMS to maintain an ongoing dialogue with practicing clinicians from relevant medical specialty and subspecialty societies beyond this comment period so that any unintended consequences of the proposed EPMs are caught early in the pilot timeframe.**

To select clinical models to be designated as proposed EPMs, CMS uses the following criteria; clinical homogeneity, site of service and reliance on MS-DRG assignment. The College's comments focus on the first criterion, clinical homogeneity, specifically in the context of the AMI model. As noted above, it is one our key topic comment area. **Failure to establish clinical**

homogeneity will increase the potential for unintended consequences, patient harm and ultimately reduce CMS' ability to evaluate the model's impact on quality and cost of care. All other recommendations provided by the College are contingent on establishing and maintaining clinical homogeneity.

Clinical Homogeneity in the AMI Model

CMS proposes to include beneficiaries who are discharged under AMI MS-DRGs 280-282 and PCI MS-DRGs 246-251 with an AMI ICD-10 CM diagnosis code in the principal or secondary diagnosis code position. **The ACC disagrees with the Agency's proposal. The ACC strongly recommends limiting the AMI model to STEMI patients discharged under AMI MS-DRGs and PCI MS-DRGs with an AMI ICD-10 CM code only in the *principal* diagnosis code position.** Episode of care models are built on the concept of clinical homogeneity. Hospital coding is relatively straightforward for procedural or surgical-based models such as the Comprehensive Care for Joint Replacement (CJR) model and the proposed CABG model. A medical diagnosis based model, such as the proposed AMI model, is inherently more complex and difficult to define as AMI is not a single defined entity. Therefore, it is crucial for CMS to limit ambiguity within model as much as possible. Substantial work over the past few decades has been done to achieve more clarity surrounding the universal definition for AMI. Under the most current consensus driven definition of AMI, the third universal definition, AMI refers to:

"evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischemia. Under these conditions, any one of the following criteria meets the diagnosis for MI:

- Detection of a rise and/or fall of cardiac biomarker values, preferably cardiac troponin with at least one value above the 99th percentile upper reference limit; **and at least one of the following:**
    - Symptoms of ischemia;
    - New or presumed new significant ST-segment–T wave (ST–T) changes or new left bundle branch block (LBBB);
    - Development of pathological Q waves in the ECG;
    - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality; and
    - Identification of an intracoronary thrombus by angiography or autopsy.[1]"

Clearly defining AMI is essential to appropriately testing this model. A clear definition will allow sites to accurately and completely report diagnoses triggering the episode. Current hospital codes do not necessarily capture the full definition. **Consequently, what is coded as AMI often only meets this definition *in part* and may be limited to abnormal biomarkers that can be detected without an acute occlusion of a coronary artery.** A relatively typical example is interpreting changes in troponin levels as an AMI without considering other clinical indicators.

[1] Thygesen K., Alpert J.S., Jaffe A.S., et al and the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. *Circulation*. 2012;126:2020-2035

This example epitomizes the necessity of a clear definition. This example was and remains so common place that it drove the need for *ACCF Expert Consensus Document on Practical Clinical Considerations in the Interpretation of Troponin Elevations* authored by experts representing the ACC and cardiovascular subspecialty societies.[2] **As a result, *aligning coding with clinical reality* will be necessary for establishing clinical homogeneity in the AMI model**.

Including in the model patients with not only a principal, but secondary diagnosis of AMI, will make it difficult to establish a clearly defined clinically homogenous population for the following reasons:

- Critically ill patients often receive a secondary diagnosis of AMI for what is more correctly characterized as supply-demand ischemia; the accuracy of the AMI diagnosis may be questionable due to the routine and inaccurate coding of any troponin leak or elevation as an AMI even when the troponin has been measured despite the absence of a clinical event suggestive of infarction
- Outcomes and cost of care for critically ill patients with a secondary AMI diagnosis are likely driven more by the primary condition than by AMI resulting from possible CAD;
- Patterns of care are very different for patients with a secondary as compared to a primary diagnosis of AMI; and
- Including patients with a secondary diagnosis of AMI increases the variability within the model, limiting opportunity to draw clear conclusions when testing the model

These points are explained below.

Critically ill patients often receive a secondary diagnosis of AMI for what is more correctly characterized as supply-demand ischemia; the accuracy of this diagnosis may be questionable due to the routine and inaccurate coding of any troponin leak or elevation as an AMI even when the troponin has been measured despite the absence of a clinical event suggestive of infarction

AMI is frequently coded as a secondary diagnosis for patients with critical illnesses. The accuracy of this diagnosis is often questionable as it is a relatively common practice in hospital coding to code *any* cardiac troponin leak or elevation, *absent other clinical indicators*, as AMI. Consider the following example of a patient with critical illness: an elderly female presenting with a significant malignancy, metastatic breast cancer, and internal bleeding who also exhibits a slight cardiac troponin leak. Due to the cardiac troponin leak, AMI is likely to be coded as a secondary diagnosis. However, based on the universal definition, clinical suspicion of AMI may likely be low. In another example, a critically ill patient, an elderly male exhibits multi-organ failure and a borderline increase in cardiac troponin levels. Due to the increase in cardiac troponin levels, however minimal, AMI may be coded as a secondary diagnosis for this patient. Many patients with multi-organ failure exhibit a change in troponin levels. Importantly, it is widely cited that small elevations or leaks in troponin are caused by many conditions, not

[2] Newby L., Jesse R.L., Babb J.D., et al. ACCF 2012 Expert Consensus Document on Practical Clinical Considerations in the Interpretation of Troponin Elevations: A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol.* 2012;60(23):2427-2463.

necessarily CAD.[34] In such patients, based on previous studies, there is a high likelihood that the root cause of the change is not necessarily AMI caused by CAD.

Additionally, ordering of troponin tests is not standardized nor is it well regulated. There is the possibility that troponins will be ordered in patients for whom there is no clinical suspicion of myocardial infarction with the hope that someone with a low risk profile can be labelled as an NSTEMI for purposes of the bundle. This unintended consequence underscores the importance of limiting the episode population to those with STEMIs where there is clear cut evidence of acute coronary occlusion. As discussed in the proposed rule, CMS is aware that is necessary to clearly identify beneficiaries to be included in the model.

Outcomes and cost of care for critically ill patients with a secondary AMI diagnosis are likely driven more by the primary condition than by AMI resulting from possible CAD

Whether AMI is the product of the primary condition or complications caused by the primary condition, or other possible factors including but not limited to coronary artery disease is key. Keeping in mind the patient examples above, for the elderly female patient, the primary condition is the metastatic breast cancer, which is likely to be considerably driving outcomes. For the patient with multi-organ failure, the condition that is chiefly responsible for causing the multi-organ failure is likely to have more bearing on the patient's ultimate outcome than possible underlying coronary artery disease. For critically ill patients, coding of AMI as a secondary diagnosis does not necessarily match clinical reality for what is primarily responsible for driving outcomes. Elderly patients with heart failure or rapid atrial fibrillation may also have the same coding in effect. For these patients, heart failure or atrial fibrillation, not AMI, is driving decisions about care, and thus costs and outcomes. **The priority should be focusing efforts on treating the primary condition. Shifting the focus could cause unintended harm to the patient.**

Consequently, it is necessary to address CMS' rationale for including percutaneous coronary intervention (PCI) MS-DRGs with an ICD-10 CM diagnosis code of AMI in the principal or secondary position. On page 50830 of the proposed rule, CMS states its rationale is "to ensure that beneficiaries with an AMI that is not chiefly responsible for occasioning the hospitalization are included in the AMI model because the AMI itself is likely to substantially influence the hospitalization and post-discharge recovery (and be responsible for leading to the PCI) even if an AMI ICD-10 CM diagnosis code is reported in a secondary diagnosis code position[5]." **However, ACC believes this assumption of CMS is incorrect. From the perspective of practicing cardiologists and members of the cardiovascular care team, for patients with severe complications and comorbid conditions, the majority of Medicare beneficiaries with cardiovascular disease, the primary condition is likely to have more bearing on outcomes than even the most aggressive care for AMI**.

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[3] De Lemos JA. Increasingly Sensitive Assays for Cardiac Troponins: A Review. *JAMA*. 2013;309(21):2262-2269. doi:10.1001/jama.2013.5809.

[4] Rahman A1, Broadley SA. Review article: elevated troponin: diagnostic gold or fool's gold? *Emerg Med Australas*. 2014 Apr;26(2):125-30.

[5] Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Proposed Rule, *Federal Register*, August 2, 2016.

Patterns of care are very different for patients with a secondary as compared to a primary diagnosis of AMI

Patients with critical illnesses and a secondary diagnosis of AMI, often have life-threatening complications such as cardiogenic shock and perioperative ischemia as well as significant comorbidities. This results in *many more clinical factors* contributing to care needs than patients with a primary diagnosis of AMI. For critically ill patients, due to varying principal diagnoses, care needs and thus patterns will likely differ. Subsequently, care design efforts are likely to vary substantially for patients with a secondary diagnosis of AMI when compared to patients with a primary diagnosis of AMI.

Including patients with a secondary diagnosis of AMI increases the variability within the model, limiting opportunity to draw clear conclusions when testing the model

According to the third universal definition of AMI consensus document, "MI may be the first manifestation of coronary artery disease (CAD) or it may occur, repeatedly, in patients with established disease[6]." The AMI model, if not limited to a principal diagnosis of AMI, would capture an entire spectrum of patients, ranging from those with acute coronary artery occlusion with substantial myocardium at risk for necrosis to those with a slight elevation in cardiac troponin levels in the context of terminal malignancies. This would include patients with acute kidney disease, internal bleeding among other issues. Although the intent of including AMI as a secondary diagnosis is to prevent and treat possible underlying coronary artery disease, including these patients would introduce an inordinate amount of variation. Risk adjustment cannot account for all the complexities across these patient types. **Such a clinically heterogeneous population will make it difficult to draw meaningful comparisons among patients. This would ultimately impact the ability of CMS to derive clear conclusions of the AMI model's impact rendering the test of the model ineffective**.

In comparison to patients with ST elevation (STEMI), the non-ST elevation (NSTEMI) patient population is more clinically heterogeneous and the diagnostic process for these patients is much more complex.

Patients experiencing an AMI generally fall into two subsets, those with ST Elevation (STEMI) and those with Non-ST Elevation (NSTEMI). NSTEMI patients are more heterogeneous in comparison to those with STEMI because of substantial differences in the underlying pathophysiology as well as appropriate approached to evaluation and management. While STEMIs occur due to an acute coronary artery occlusion, many NSTEMIs occur when the coronary arteries remain open but where there is an imbalance between the oxygen demands of the heart and the coronary arteries ability to meet them – this is called supply-demand ischemia. By nature, much more variation in clinical presentation occurs in NSTEMI patients. The AMI model should only include STEMI patients, which when risk adjustment is applied, represents a more homogenous population compared to NSTEMI patients

[6] Thygesen K., Alpert J.S., Jaffe A.S., et al and the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. *Circulation*. 2012;126:2020-2035

Distinguishing between subtypes of AMI can be challenging. Changes in cardiac troponin levels are often coded as AMI in a secondary diagnosis position for patients with critical illnesses. These are frequently type 2 AMIs, a subtype of AMI that is a myocardial injury related to a supply and demand mismatch. Importantly, type 2 MI occurs when conditions other than CAD contribute to an acute imbalance between oxygen supply and demand.[7] The concern is that a supply and demand mismatch does not necessarily correlate with the degree or stability of underlying CAD. Indeed troponins may be released when coronary arteries are not abnormal but a combination of high demand and reduced perfusion pressure make it impossible for even normal coronary arteries to supply enough oxygenated blood to the heart, for example in patients with critical aortic stenosis or hypertrophic cardiomyopathy. This concern has been widely cited in the literature.[8][9][10] It is common to consider "type 2" AMIs as NSTEMI. **The AMI should not be the focus of the care coordination, when for many of the NSTEMI patients, comorbid conditions are the major determinants of outcomes. Those comorbidities, not the AMI, should be the focus of care.**

Type 1 AMI occurs due to a primary coronary event such as a plaque rupture or thrombotic occlusion[11]. To properly capture the variability in the clinical events resulting in AMIs other than type 1, essential in assessing the impact of the proposed EPM, will be impossible. The new ICD-10-CM codes, to be updated in October of 2016, better capture the definition of AMI as all STEMI patients will be distinguished as having type 1 AMI. Additionally, arriving at a STEMI diagnosis is fairly straightforward since the electrocardiography (ECG) findings required to support this diagnosis are clear.

For the reasons above, limiting inclusion in the AMI model to STEMI patients with a principal diagnosis of AMI is necessary. This group of patients is the most homogenous clinical subset of patients assigned to AMI or PCI MS-DRGs at discharge. Hospital coding is most likely to align with clinical reality for this population of patients. Limiting inclusion in the AMI model to this subset of patients will allow for meaningful comparisons among patients, providing CMS the opportunity to clearly evaluate the impact of EPMs on patient care and outcomes.

Exclusion of cardiogenic shock and sepsis patients

CMS does not propose excluding AMI patients based on clinical features or complications other than end-stage renal disease (ESRD). **In addition to ESRD, the College strongly recommends excluding cardiogenic shock and sepsis patients, two patient subsets that generally have a higher mortality rate in comparison to other cardiac conditions.** Patients in cardiogenic shock and those with sepsis represent two patient subsets where patient prognosis is poor where

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[7] Baron et. al. et al. *Heart*. 2015 Jan;101(2):101-6.
[8] Sandoval et. al. Supply/demand type 2 myocardial Infarction: should we be paying more attention? *J Am Coll Cardiol*. 2014;63(20):2079-2087.
[9] Collinson P, Lindahl B. Type 2 myocardial infarction: the chimaera of cardiology? *Heart* 2015;101:1697-703.
[10] Collinson P, Lindahl B. Diagnosing type 2 myocardial infarction. *American College of Cardiology* website. 2018. Accessed September 15, 2016.
http://www.acc.org/latest-in-cardiology/articles/2016/05/18/13/58/diagnosing-type-2-myocardial-infarction
[11] Thygesen K., Alpert J.S., Jaffe A.S., et al and the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. Circulation. 2012;126:2020-2035

little opportunity for outcome improvement exists regardless of care provided. These patients have a substantially higher mortality rate compared to many other patient cohorts, although some may be saved with high intensity and typically costly intervention. Patient selection is a key concern for these patients and unintended consequences cannot be understated. Under the proposed EPM, high intensity care might unreasonably be withheld from these sickest, most critically ill patients while those that are more easily treated (and are at lower risk for mortality) may be more likely to receive adequate care. Risk adjustment is helpful, but only to a certain extent. Risk adjustment methodology varies and if risk adjustment is perceived as being inadequate, it is possible patients at higher risk may be avoided. This depends on the physician's and hospital's confidence in the risk adjustment methodology. The lower the confidence level, the more risk-avoidance behaviors can be expected to occur.

AMI Model Quality Measures

CMS proposes weighting the 30-day risk-standardized mortality rate (RSMR) at 50% of the composite quality score. The ACC disagrees with this. **The ACC strongly recommends reducing the weighting for the (RSMR) in the AMI model to no more than 30% of the composite quality performance score.** The high weight assigned to the risk-standardized 30-day mortality rate could result in unintended consequences and thus needs to be reexamined by CMS. One unintended consequence of such a high weighting for mortality rate is that it is possible to encourage certain providers to perform total revascularization even when not clinically indicated at the time of the acute event. There are also other unintended consequences. As previously stated, the College strongly recommends excluding cardiogenic shock and sepsis patients as patients with AMI who have either of these conditions have a higher mortality rate than those who do not. If these patients are excluded from the design of the model, they should also be excluded for measurement purposes. For some patients included in the model, the cause of death may not be related to inadequate care or uncontrolled, poorly managed CAD. Patients with cardiovascular disease that has already progressed to such an extent, regardless of the care given, are most likely to rapidly deteriorate with death as the outcome. ACC believes that entities and clinicians not be measured on situations in which they have little to no control of the outcomes for patients.

The ACC's comments for the FY 2016 Hospital Inpatient Prospective Payment System proposed rule did not support the inclusion of the Excess Days in Acute Care Hospitalization for AMI (NQF #2431) measure in the Hospital IQR Program for FY 2018 which coincides with the pilot timeline. The ACC continues to have concerns over whether these post-discharge acute event measures should be used to assess the quality of care. While the EPM pilot program includes patients for a 90 day period post inpatient discharge, ACC encourages CMS to consider our prior comments as they assess the performance of hospitals where external factors such as patient expectations, health literacy, lack of caregiver support and socioeconomic conditions that affect as patient's ability to comply with the appropriate follow up care contribute to the rate of post-discharge hospitalizations.

Additional considerations of appropriate quality measures and use of registries to report data

If CMS lowers the RSMR weight to no more than 30% of the quality score, CMS should consider reallocating the remaining 20% of the weight to relevant measures, as appropriate, from the Core Quality Measure Collaborative (CQMC) Cardiovascular core quality measures set along with measures reported through the ACC's National Cardiovascular Data Registry (NCDR®) as these measures would be valuable in evaluating the overall success of the model. Another measure to consider in evaluating the overall success of the AMI model is defect free care for AMI, a composite patient level measure (NQF #2377). This measure has been suggested for future inclusion in the next version of the CQMC cardiovascular core quality measure set.

The NCDR® is the ACC's suite of cardiovascular data registries consisting of 8 hospital registries and 2 outpatient registries, helping hospitals and private practices measure and improve the quality of care they provide. NCDR is a well-established data registry with a robust data set. Two registries within NCDR that are particularly relevant for the AMI model are the ACTION Registry®-GWTG™ and CathPCI Registry®. The ACTION Registry®–GWTG™ is a risk-adjusted, outcomes-based quality improvement program that focuses exclusively on high-risk STEMI/NSTEMI patients. It helps hospitals apply ACC/AHA clinical guideline recommendations in their facilities and provides invaluable tools to measure care and achieve quality improvement goals. The CathPCI Registry® assesses the characteristics, treatments and outcomes of cardiac disease patients who receive diagnostic catheterization and/or PCI procedures. This powerful tool captures the data that measure adherence to ACC/AHA clinical practice guideline recommendations, procedure performance standards and appropriate use criteria for coronary revascularization. **The ACC believes it would be a missed opportunity not to incorporate additional measure data captured by the NCDR registry into quality performance reporting, and strongly advocates for the use of NCDR registries to support measurement efforts for the EPM models**.

While generally supportive of the concept of combining meaningful clinical and claims data to create a voluntary Hybrid AMI Mortality measure (NQF #2473), the ACC remains cautious about the feasibility of implementing this measure. The process of combining meaningful clinical data and claims data in an electronic format is a laudable endeavor. A hybrid measure requiring review of administrative data to determine measure population will increase the reporting burden for hospitals, particularly for their clinical abstracters and coders.

Patient Reported Outcomes Measures (PROMs) and Quality of Life (QOL) measures

The ACC recommends exploring the opportunity to develop and implement patient reported outcomes and quality of life measures in the AMI model. To reiterate ACC's comments regarding the CMS Quality Measure Development Plan, CMS should explore the development of new PROMs that use patient-reported data such as blood pressure logs, daily weight measurements, and daily activity logs as true outcome measures. Increasingly, clinical evidence shows that this data can produce a more accurate picture of a patient's overall health status compared to periodic clinician-reported data alone. The ACC recognizes that developing and implementing these measures will require time and effort; however, when utilized with evidence-based quality measures, they have the potential to provide a robust view of a patient's condition.

When utilized appropriately, PROMs have the potential to provide an accurate reflection of patient outcomes; however, when implementing PROMs in Medicare quality and

payment programs, CMS should exercise caution to ensure that these measures do not hold clinicians responsible for patient choices and actions that are outside of the clinicians' control. CMS must recognize the accountability of both the patients and caregivers who are reporting the outcomes either through the design of these measures or through the way that they are implemented into programs. For example under MACRA, a clinician's MIPS quality score should not be negatively impacted by a patient who reports his or her health as poor if it is discovered that the patient did not adhere to a previously discussed treatment plan or prescribed medication. As CMS explores the increased use of PROMs under MACRA for MIPS and APM quality reporting activities, the agency should look for ways to promote the adoption of PROMs while recognizing the autonomy of the patient outside of the clinical setting.

Advanced APMs

ACC is pleased with the opportunity created for cardiologists and the cardiovascular care team to participate in AMI and CABG EPMs that have the potential to be designated as Advanced APMs under MACRA, provided participants meet certified EHR technology (CEHRT) requirements.

The ACC strongly supports opportunities for specialists to participate in Advanced APMs. The ACC is also particularly encouraged by the opportunity for a future Bundled Payments for Care Improvement (BPCI) model to be designated as an Advanced APM. The ACC continues to strongly support further opportunities to include specialists in Advanced APMs as noted in the College's response to the MACRA proposed rule.

The ACC recognizes that Qualified APM Participant (QP) thresholds will be set according to the final MACRA rule and that CMS is not proposing a change here. **However, the ACC strongly recommends lowering the patient count and payment revenue thresholds to meet Qualifying APM Participant (QP) status under MACRA.** The prospect of participating in EPMs designated as Advanced APMs represents a true opportunity. QP thresholds that are not reasonably achievable by the vast majority of clinicians eligible to participate in EPMs render this opportunity unattainable. Even with implementing both the AMI and CABG models in the same Metropolitan Statistical Areas (MSAs), it will be very challenging for a provider to have sufficient volume of Medicare beneficiaries to meet thresholds as specified in the MACRA proposed rule. Cardiologists and other specialty physicians treat high risk, high cost patients whose complications, comorbidities and care locations are diverse. Meeting thresholds will depend on size and penetration of the participants' local APMs. It will also be difficult for small independent multispecialty groups, some cardiology group practices, and solo practitioners to achieve the patient volume needed to meet thresholds proposed. Larger entities such as accountable care organizations (ACOs), with a high number of covered lives, will have a greater likelihood of meeting threshold requirements.

Preparing for Assuming Risk

CMS proposes to exclude downside risk during the performance year and first quarter of the second performance year. **The ACC supports CMS' proposal to exclude downside risk, thereby holding participants harmless, during the first performance year and first quarter of the second performance year.** Implementing no downside risk in the first program year

allows providers with little experience with APMs or those that have some experience but are not quite ready to take on risk, the ability to prepare for the future program years.

Special Transfer Policies for Beneficiaries in the AMI Model

CMS proposes to attribute patients to the hospital that first admits the patient under the relevant AMI MS-DRGs (280-282) and PCI MS-DRGs (247-253). The ACC disagrees with this. **The ACC strongly recommends attributing patients to the hospital where revascularization procedures are performed rather than the anchor hospital as the admitting hospital that transfers the patient for treatment has little or no control over the rest of the episode and thus should not be held accountable.** Many smaller hospitals that initially admit patients to be included in the AMI model encounter the need to transfer patients. The ACC is concerned that it is an unrealistic expectation to minimize shifting of patients outside of MSAs during a 90 day period. Patients may receive revascularization care outside of their home MSA and then return afterwards to be rehospitalized in their local hospital. It is unclear how this situation will be addressed.

Risk Sharing and Financial Arrangements under EPMs

The ACC supports the proposal that the hospital be the primary responsible risk-bearing entity in the AMI model. Hospitals, rather than physicians, likely have the infrastructure to be more prepared to assume and manage financial risk. However, is important to consider the diversity of hospital experience with APMs when developing risk-sharing policies and thresholds. Some hospitals have experience with APM participation, while others have not. Some hospitals will be able to assume financial risk, yet those with less experience will have a short time window to adapt or prepare in advance for implementation of the proposed EPMs. Hospital readiness and capabilities for providing appropriate services will be important to assess and monitor when considering the potential impact of the AMI and CABG models in the metropolitan statistical areas (MSAs) selected.

In the proposed AMI and CABG EPMs, physicians will continue to be reimbursed via fee-for-service, however, CMS proposes to also share up to 50% of total savings achieved via Part B services with physicians. **The ACC strongly recommends including both Part A and Part B services in gainsharing arrangements to achieve truly meaningful risk sharing.** Meaningful gainsharing assists in aligning incentives. Accounting for unplanned care necessitating Part B services is critical. To improve patient outcomes, unplanned clinically appropriate care must be accounted for resulting in potentially more physician involvement than originally anticipated. In the AMI model, unplanned care may be necessary for congestive heart failure, rhythm and valvular issues, and cardiac imaging of ischemia. Previous demonstrations such as the Medicare Acute Care Episode (ACE) Demonstration, resulted in strong qualitative evidence of effectively increasing care coordination, laying the groundwork for true meaningful collaboration. **Significant reductions in Part A costs may be achieved through reducing length of stay to and unnecessary readmissions, but those savings are unlikely to be accomplished without active physician participation**. **Physicians should then be eligible to share in those Part A savings.**

Additional Care Coordination Considerations

The ACC has gained insight and experience through its Patient Navigator and the Surviving AMI (SAMI) programs. **The ACC urges CMS to make resources for care coordination strategies available to support advancing care coordination through appropriate pre-discharge planning and post-discharge follow up. ACC would welcome the opportunity to work with CMS to make such resources available to participants in the EPM.** The EPM provides an opportunity to encourage care coordination beyond the physician including the cardiovascular team. The majority of opportunities to advance care coordination and improve patient outcomes are in decreasing hospital length of stay to only what is necessary for appropriate treatment, to prevent unnecessary readmissions and to control post-acute care costs. However, it is critical to recognize physicians may have less control over post-acute care patterns contributing to readmissions, particularly if patients are non-adherent and when the duration of the episode is 90 days.

Opportunities during hospitalization

Major opportunities to improve care coordination include strong pre-discharge planning activities, prevention of unnecessary patient visits to the emergency department through early recognition of decompensation, increasing appropriate referral to cardiac rehabilitation services, as well as effective patient and family education. Ensuring the *social and environmental components* are in place prior to discharge is critical. Communication of the most appropriate post-acute care facilities to not only the patients, but their families and caregivers can be essential to a patient's recovery.

Opportunities post-discharge

Appropriate follow-up care will be critical to advance care coordination and better health outcomes for patients. Ensuring tighter pharmacy adherence, including medication reconciliation and emphasizing preventative care (including regular follow-up visits) will play a large role in improving patients' health and potentially decreasing subsequent readmissions. Many readmissions are due to poor medication reconciliation and poor coordination of care post-discharge. Improved pharmacy adherence would include ensuring patients have access to and obtain their medicines in a timely fashion, ensuring patients understand the medication regimen provided to them post-hospitalization as well as resuming and reviewing previously prescribed medications. Scheduling a clinic visit within a short time interval following discharge could influence the course of the patient's post-acute care experience. ACC has several quality improvement (QI) programs in place to support opportunities following discharge of patients such as the Hospital to Home (H2H) and Surviving AMI (SAMI) Initiatives. H2H facilitates patients' transition from the hospital to their home while SAMI helps hospitals with reducing risk-standardized mortality rates, addresses cultural change and engage senior leadership with quality improvement efforts.

It is critical to recognize hospitals and clinicians may have little control over post-acute care patterns. If patients are non-adherent with clinician recommendations, for example with medication regimens or other treatment requirements, hospitals and clinicians should be not be penalized in these scenarios.

CARDIAC REHABILITATION (CR) INCENTIVE PAYMENT MODEL

Following discharge from the hospital, many AMI and CABG patients benefit significantly from cardiac rehabilitation services. The College appreciates the opportunity to provide comments on the Cardiac Rehabilitation (CR) Incentive Payment Model and is truly pleased with the emphasis on encouraging increased utilization cardiac rehabilitation services. As CR is historically an underutilized service, there is considerable room for improvement in increasing enrollment in cardiac rehabilitation services. The College is supportive of incentives designed to appropriately increase use of cardiac rehabilitation services. The CR Incentive Payment Model represents an opportunity to truly positively impact cardiac rehabilitation across the country. The College provides the following comments on the cardiac rehabilitation payment incentive model and continues to support incentives to increase access to and use of cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services.

Cardiac rehabilitation services are critical to advancing patient care. As discussed in the proposed rule, increased referral of patients and their subsequent enrollment in cardiac rehabilitation services has been shown to reduce readmission rates. The college provides the following recommendations.

Interplay with HR 3355/S. 488

The ACC supports the HR 3355/S. 488, a bill that would expand access to cardiac rehabilitation by allowing physicians assistants, nurse practitioners and clinical nurse specialists to supervise cardiac, intensive cardiac and pulmonary rehabilitation programs. The College continues to support passage of this bill even with the introduction of the proposed cardiac rehabilitation incentive payment model. We hope that CMS will be able to provide Congress with data from this demonstration project that supports the value of cardiac rehabilitation.

Physician supervision waiver

CMS proposes to implement the physician supervision waiver only for AMI and CABG patients. **However, ACC strongly recommends implementation of a site-specific rather than a condition-specific physician supervision waiver.** The ACC is concerned with inconsistencies regarding physician supervision issues. If the physician supervision provision in the proposed rule to include licensed advanced practice nurses is extended only to patients released under the specified AMI and CABG MS-DRGs (rather than all Medicare approved diagnoses) many programs will still require physician supervision of cardiac rehabilitation sessions for some program participants. As a result, the added flexibility will not occur in practice, limiting its intended effect. The proposed physician supervision waiver should be extended to all patients participating in cardiac rehabilitation at designated institutions.

CR incentive payment considerations

ACC supports the proposal to use the cardiac rehabilitation incentive payment, in part, to subsidize transportation as it is a fundamental beneficiary engagement incentive, as outlined in the proposed rule. Subsidizing transportation will increase access to CR and ICR

services. Additionally, opportunity exists to include related costs such as parking. CMS recognizes transportation is a barrier to cardiac rehabilitation and the College strongly agrees.

ACC supports additional considerations for using the incentive payment to support beneficiary engagement incentives that foster a heart healthy lifestyle. It is important for beneficiary engagement incentives to foster heart healthy lifestyle changes. As a result, there is opportunity that fosters continuation of these lifestyle changes which would be appropriate and further enhance the effectiveness of Phase 2 cardiac rehabilitation. For example, incentives could include payments or vouchers for continued enrollment in exercise programs (such as Phase 3), diet/nutrition services and tobacco cessation services. Another possibility is payment for a preventative cardiology visit following Phase 2 completion for review and reassessment of patient centric goals. Another incentive would be to improve availability by increasing time of operation for available services. In terms of patient engagement, creating processes to involve caregivers and patient support systems will be critical.

ACC strongly recommends CR incentive payment be used to in part, to gradually lower patients' co-payments for CR services provided they continue to adhere to cardiac rehabilitation regimen requirements as they progress through the course of rehabilitation. There is consensus among many providers of CR and/or ICR services that potential payments with high cumulative copays serve as significant barriers to obtaining these services. The ability to utilize the incentive to decrease this cumulative copay would assist in increasing CR and/or ICR services utilization, provided the patient consistently adheres to cardiac regimen requirements.

The ACC recommends increasing reimbursement for the initial session of CR/ICR services provided to the patient from $25 to $175 as this first session is fundamental to enrolling the patient and beginning the rehabilitation process. This will ultimately enhance patients' progress. The initial evaluation, enrollment, and education of the patient for cardiac rehabilitation is very resource intensive. Increasing the incentive for the first session would better reflect actual costs as well as incentivize programs to incorporate as many patients as possible to the use of cardiac rehabilitation services.

ACC recommends permitting sharing of incentive payments with appropriate institutions. It is important for designated institutions to be able to share the CR incentive payment with other institutions, as appropriate. For example, a tertiary care center may receive referral patients for CABG or treatment of AMI from distant institutions with limited CR services. The patient, for geographic reasons, is compelled to receive CR services at the referring institution. Directing some of the incentive payment to this referring institution to augment CR services, for example extra classes and/or extended hours may be necessary and appropriate.

CONCLUSION

ACC is committed to working with CMS and providers to foster success in the new value-based payment environment. The proposed AMI and CABG EPMs represent an initial step in creating opportunities for cardiologists and the cardiovascular care team to participate in Advanced APMs. This continued movement towards a value-based payment system that rewards all

clinicians, including both specialists and primary care physicians, will need to be implemented and monitored carefully to avoid unintended consequences for patients.

It is difficult to understand the impact mandatory bundled or episodic payments may have on patient care without fully understanding the impact of the recently implemented Comprehensive Care for Joint Replacement (CJR) mandatory bundle. While this is a procedure-based mandatory bundle, with different disease characteristics, it is still very early to evaluate any unintended consequences. Additionally, for the proposed AMI and CABG EPMs, the most relevant bundled payment effort is the Bundled Payments for Care Improvement (BPCI). Although the year 2 evaluation and monitoring report[12] was recently released, the data only shows up to 15 months of participation. Additionally, as the authors convey, the data does not reflect the increase in uptake due to limited sample size nor does it reflect reconciliation payments received. We look forward to the next evaluation report in the series to gauge how participants and patients will fare.

How CMS monitors the implementation of the proposed AMI and CABG models and evaluates the results will be critical to understanding the effects of this model. There is a great need to guard against patient harm and unwarranted disruptions to communities' systems care delivery for AMI and CABG patients. ACC's NCDR® registries may be helpful in this regard. ACC will closely monitor implementation and provide support to our members, as appropriate, based on their selection as part of this 5 year pilot program. During the evaluation process it will be critical to consider the impact of this model on patient outcomes including quality of life if CMS chooses to expand these models nationally post-pilot timeframe. Success should not be judged solely on cost savings. It will be crucial that CMS work with cardiologists and members of the cardiovascular care team to implement an infrastructure that supports care coordination and protects patients from unintended consequences.

Finally, the College continues to strongly support delivery and payment models that encourage access to and use of cardiac rehabilitation services including the proposed CR incentive payment model.

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 require additional information, please contact Pratyusha Katikaneni, Manager, Value-Based Payment Solutions at pkatikaneni@acc.org or (202) 375-6525.

Sincerely,

Richard A. Chazal, MD, FACC
President

[12] Dummit L, Marrufo G, Marshall J et. al. CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation and Monitoring Annual Report. The Lewin Group on behalf of Centers for Medicare & Medicaid Services (CMS). August 2016.