September 21, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services, Attention: CMS–5519–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Dear Mr. Slavitt,

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); Proposed Rule [CMS–5519–P]

INTRODUCTION

Thank you for the opportunity to comment on this proposed rule. Copies are available at: https://www.federalregister.gov/articles/2016/08/02/2016-17733/medicare-program-advancing-care-coordination-through-episode-payment-models-epms-cardiac

SEPERATING CABG PATIENTS FROM AMI BUNDLE

We support CMS’s proposal to have coronary artery bypass graft (CABG) procedures placed in a separate CABG only bundle. We are concerned however that the novel financial incentives in these bundles could result in unintended consequences some of which are described below.

QUALITY MEASURES

SCAI is pleased that one of the four quality measures being proposed includes a requirement for facilities to submit clinical data. We are disappointed that CMS will not be using more clinical data to assesses the reasons for poor patient outcomes. Most clinical trials used adjudicated data on the cause of death and other reported outcomes in order to determine if unfortunate outcomes were related to poor quality care. Comprehensive databases and registries (e.g. ACC/NCDR) utilize audited data collection and
risk-adjusted mortality reporting as well as other important in-hospital outcomes such as significant bleeding or liver damage. CMS should be very cautious in assessing the quality outcomes of this study without more robust data. We encourage CMS to use ACC/NCDR data from the ACTION and/or Cath/PCI registries when it is available and we will encourage ACC/NCDR to consider an external review of this experiment using the data that it will have available on most of the patients in this study.

We recommend that CMS narrow the 90-day window of this bundle for quality measures to 30 days. It is known from large, randomized controlled trials evaluating therapies for acute myocardial infarction patients that the overwhelming majority of disease-related (complications or hospitalizations related to AMI) and procedure-related poor outcomes occur within the first 30 days.\(^1\)\(^2\)\(^3\) On average, Medicare beneficiaries mortality is 0.42% per month\(^4\) Given that in-hospital mortality rates for PCI in large series from experienced operators ranged from 0.5 to 1.7 percent\(^5\) a large proportion of post procedure deaths are likely due to non procedural issues. Physicians and hospitals should not be held accountable for such unfortunate but un-related outcomes.

We are also concerned that reporting of quality data could discourage the treatment of the most vulnerable AMI patients like those in cardiogenic shock. Numerous studies have shown that public reporting can lead to less aggressive treatment of the sickest patients who could benefit

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\(^4\) Christopher Hogan, June Lunney, Jon Gabel, and Joanne Lynn Medicare Beneficiaries’ Costs Of Care In The Last Year Of Life Health Affairs, July/August 2001; 20(4): 188-195.
the most from primary PCI.\textsuperscript{6,7,8,9,10,11} We recommend that patients in cardiogenic shock and out-of-hospital cardiac arrest be excluded from this study or at least from the outcome measurement portion of this study in order to avoid dis-incentives to treat those most in need of an interventional procedure.

MULTI-VESSEL DISEASE
Another factor which concerns SCAI is that the bundle may discourage the appropriate treatment of patients with multi-vessel disease. Nearly 50 percent of STEMI patients have multivessel disease but current guidelines discourage the treatment of non-culprit vessels at the time of an AMI and the most recent update to those guidelines states:

“Although several observational studies [19,20] and a network meta-analysis [13] have suggested that multivessel staged PCI may be associated with better outcome than multivessel primary PCI, there are insufficient observational data and no randomized data at this time to inform a recommendation with regard to the optimal timing of nonculprit vessel PCI.


AMI patients with multivessel disease often should get a secondary PCI procedure but this bundling effort will discourage the recommended course of care. This bundle will encourage the treatment of secondary lesions during the initial angioplasty and in other cases there will be an incentive to delay treatment of the secondary lesions until after the 90 bundle has expired. Another strategy to cope with the capped payments under the bundling strategy might be to inappropriately refer more multi-vessel patients into the separate CABG bundle.

CMS should consider excluding patients with multivessel disease from this bundle and/or making accommodations for the extra cost of treating such patients appropriately. If the AMI bundle can’t be redesigned to avoid these perverse incentives, CMS should at least monitor and evaluate whether these shifts are occurring and whether they have affected patient outcomes.

USE OF DRUG ELUTING STENTS
Significant evidence exists demonstrating that the use of more expensive drug-eluting stents (DESs) results in better long-term outcomes in many patients and fewer repeat procedures for in-stent restenosis.¹² ¹³ That long-term benefit for patients (avoiding the risk, inconvenience and cost of secondary procedures) and to Medicare (via fewer repeat procedures in the long term) will not be fully captured in a 90-day bundle, but the full additional costs of DES will be.

CMS should take steps to ensure that the financial models used here do not discourage the appropriate use of DES. If the study causes fewer patients to receive DES, long term outcomes may deteriorate and overall costs may grow.

OUTPATIENT PCIs
It is rare for an AMI patients to be treated with PCI on an outpatient basis. We are concerned that simply excluding these patients from the bundles could lead to inappropriate incentives for hospitals to change billing to outpatient reimbursement. Some may shift their billing from inpatient to outpatient when a patient has worse outcomes or more costly treatments. We recommend that CMS but all AMI patients on their inpatient only list.

COMPLICATIONS FROM OTHER PROPOSED MEDICARE CHANGES
In CMS’s proposed physician payment rule for 2017, CMS proposes to unbundle the primary PCI payments from the incorporated moderate sedation and to force physicians to bill for this separately. We oppose this proposal for a variety of reasons but in relation to this project where CMS is bundling payments for PCI treatments we suggest that the introduction of a new physician billing system for PCI may complicate CMS’s analysis of the demonstration program. We recommend that CMS not unbundle this service, doing so just complicates billing and data.

POST DISCHARGE HOME VISITS
Within the confines of this study, SCAI considers a test of greater coverage of home visits with less physician supervision to be worthwhile. This could improve patient outcomes and should be tested.

¹² First analysis demonstrates late benefits of DES (J Am Coll Cardiol. 2015 Jun 16;65(23):2496-507).
INCLUSION OF TRANSFERRING HOSPITALS
When AMI patients are transferred to another facility for treatment there is a lot of grey area surrounding who can and/or should provide follow-up care especially if the patient lives much closer to the transferring hospital. We encourage CMS to be flexible in order to enable the best possible care for transferred patients.

EXCLUSION OF PATIENTS WITH SEVERE COMORBIDITIES
CMS is proposing to exclude some patients with higher (more costly) DRGs from this study. We agree that such an exclusion is appropriate.

EVALUATING THE DEMONSTRATION PROJECT’S SUCCESS
CMS should carefully examine the outcomes of this test before expanding the number of areas involved or the types of patients involved. We are concerned that CMS is using the ongoing comprehensive joint replacement (CJR) bundling project as a justification for this project but that study is far from being complete and it will be years until final results are known. CMS should take great care in analyzing the outcomes of this study. The treatment of AMI with either PCI or surgery is not like joint replacement. The treatment of patients with an AMI is more than just an individual procedure but rather a part of therapy in treating the larger complex disease process of atherosclerotic heart disease. This is a fundamental change in the way medicine is practiced in the United States and there are many potentially unintended consequences for patients in the bundles and those left out of the bundles.

CONCLUSION
Thank you again for the opportunity to comment on this proposed rule. We share your goal of making Medicare a more efficient and effective program for our nations seniors and disabled. If you or your staff would like to discuss these comments, please contact Wayne Powell, our Senior Director for Advocacy and Government Relations at 202.741.9869 or wpowell@scai.org

Sincerely,

Kenneth Rosenfield, MD, MHCDS, MSCAI
President