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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 24, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1599-P
PO Box 8011
Baltimore MD 21244-1850

Dear Ms. Tavenner:

The American College of Cardiology (ACC) is pleased to offer comments on the proposed rule on **Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation** as published in the Federal Register on May 10, 2013. The College's goal in commenting on these proposed regulations is to ensure that hospitalized patients with cardiovascular disease receive the best possible care.

The ACC is transforming cardiovascular care and improving heart health through continuous quality improvement, patient-centered care, payment innovation and professionalism. The College is a 43,000-member nonprofit medical society comprised of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care. More information about the association is available online at <http://www.cardiosource.org/ACC>.

CMS proposes to use new cost centers for implantable devices, cardiac catheterization, MRIs, and CTs in establishing relative weights. These four new cost centers would establish separate cost-to-charge ratios (CCR) for services assigned and would in turn affect payment for various services, including for a number of DRGs with significant involvement of cardiovascular disease. We support the principle of the CMS efforts to more reliably understand the costs of services provided in the hospital.

However, as more and more cost centers are developed in the inpatient hospital system, payment levels can be more subject to dramatic changes from year to year. For example, the creation of a cardiac catheterization cost center dramatically reduces both the number of cases and the number of hospitals for which data is gathered. We urge CMS to carefully proceed in the use of these new cost centers. While there is relatively limited effect on payment levels within the inpatient system, we anticipate that there will be much more dramatic effect on the outpatient system, where the units of service are much smaller. The large changes in the CCR for services such as CT and MR may be reflective of different costs or they could reflect data anomalies coming from inexperience with the new accounting measures. The decisions that CMS make on payment have wide ranging impact on elements of care so we urge caution even as we support the efforts for more precise measurement.

Tissue Plasminogen Activator (tPA) Administration with 24 hours prior to Admission

CMS notes that it has received comments from hospitals that receive patients transferred from other facilities following the administration of TPA for stroke. A higher payment is associated with the use of TPA or a similar agent, generally reflecting a more acute patient. In the case of a transfer, the receiving hospital does not administer the TPA and is therefore not eligible for the higher payment. However, the more acute patient is still being cared for at the level required of a patient who received TPA. In this rule, CMS proposes to establish TPA administration within 24 hours as a complicating condition for stroke patients, thus recognizing the increased costs associated with these patients. The ACC does not have the detail to determine if the analysis performed by CMS reflects the true costs, but we are very supportive of the intention to recognize the increased costs associated with receiving transferred patients. We believe that any MS-DRG constructed in which a particular service or procedure is a key element needs to be monitored to ensure that the intent of the MS-DRG system, paying for the severity of the patient, is maintained.

Discharge/Transfer to Designated Disaster Alternate Care Site

The ACC supports the CMS proposal to add patient discharge code 69 to the MS-DRG Grouper logic for MS-DRGs 280-282 used for acute myocardial infarction. As we understand it, this new discharge code will allow hospitals to be paid for their services in treating patients with AMI even if they have to transfer the patient in the event of a natural disaster. This discharge status will be rarely used but is needed.

Discharges/Transfers with a Planned Acute Care Hospital Inpatient Readmission

CMS proposes to add 15 new discharge status codes that will help to identify planned readmissions following AMI. We are supportive of the CMS effort to track planned readmissions. The increased focus on readmissions, with both public reporting of measures and the expanded hospital readmission penalty program, means that it is very important to separate planned from unplanned readmissions. The proposed rule did not include a discussion of how

these new code edits might be integrated into the measurement of readmissions in the future. We hope that CMS will address this integration through public comments in the near future.

Chronic Total Occlusion of Artery of the Extremities Diagnosis Code

We support the CMS proposal to remove atherosclerosis and aneurysm codes from the complicating condition exclusion list for diagnosis code 440.4 used for chronic total occlusion (CTO) of arteries of the extremities. If this proposal were implemented, patients with chronic total occlusion of arteries of the extremities would be considered to have higher acuity and be eligible for payments under the MS-DRG with a complicating condition. We agree with CMS that aneurysms are not clinically closely related to peripheral CTOs. In addition we agree with CMS that a patient with a peripheral CTO has much more severe disease than a typical patient with atherosclerosis and the use of the code for a CTO represents a complicating condition even in those patients.

Add-on Payments for New Services and Technology

The ACC does not support the CMS proposal to eliminate the annual in-person town hall meeting on add-on payments. CMS notes that approximately 60 people attended the meeting in person in Baltimore so there is clearly interest. This interest would be particularly acute on the part of those parties which are seeking add-on payments for particular technologies. Limiting the meeting to a “virtual town hall” may give less of a voice to those applicants. We are pleased that CMS has offered the option to observe the session via Internet live-stream, but would not support the elimination of the in-person option.

Mitral Valve Clip

CMS has requested comments on the establishment of a new technology add-on payment for mitral valve clip services, used to repair mitral valves through a catheter in patients who are not surgical candidates. CMS requires that services received new technology add-on payments must be new, have costs that are not covered by the DRG in which it is placed, and offer significant improvement over existing services and technologies. We believe that the newness of this technology is fairly self-evident with the first device awaiting FDA pre-market approval following a recent advisory panel meeting but will offer comments on the other two elements.

Mitral valve clip services are much more expensive than the percutaneous cardiovascular procedures such as angioplasty without stent that are reimbursed in DRGs 250 and 251. In previous comments, we have criticized the placement of transcatheter mitral valve repair in this category as we believe it is more appropriately placed in DRGs 216-221 used for cardiac valve and other major cardiothoracic procedures. We still believe that this would be the appropriate DRG placement. This is consistent with the DRG placement services for other transcatheter valve replacement procedures such as transcatheter aortic valve replacement.

CMS has pointed to a cost analysis that shows similar costs of mitral valve clip and angioplasty cases. We believe that this reflects an ongoing problem with the pricing of new technology which involves expensive devices such as this valve replacement. Because hospitals are participating in clinical trials, they are reporting reduced costs of the device associated with the trial instead of the commercial cost for the device once it comes to market. While the commercial price would eventually be reported through cost reports following FDA approval, the CMS rate-setting process takes a number of years to recognize this. As hospitals come under greater and greater cost restraints, they may be dissuaded from implementing new and helpful technology by this delay. In the long term, this can prevent patients from having access to the latest treatment options. If CMS chooses to keep the percutaneous mitral valve repair in the current DRG, it appears that the cost of the valve and other associated services would cause the payment to be inadequate.

Transcatheter mitral valve clip services will be a significant improvement in current services because they will be used for patients who are too high risk for a surgical mitral valve repair or replacement. For these patients, the current standard is medical therapy. Mortality rates for patients who received the transcatheter therapy were lower than those who received the alternative medical therapy, according to a recent study. While more evidence needs to be collected, we believe that this evidence meets the standards required by CMS.

In short, we believe that there is great potential for transcatheter mitral valve repair for patients who do not currently have access to treatment. **In order for this service to be available to Medicare beneficiaries, CMS must recognize the costs associated with this new technology and pay part of them through the new technology add-on payment.** This temporary add-on payment will allow the bridge for data to be collected and further integrated into the DRG system.

Hospital Readmission Reductions Program

As required by statute, CMS is increasing the maximum penalty associated with excess readmissions from 1% in 2013 to 2% in 2014. We wish to express our ongoing concern about this penalty program. Because readmission rates are determined by a three year average, hospitals are being judged based on discharges going as far back as 2009, before the current focus on readmissions began. In addition, because of the three year measurement, it will be difficult if not impossible for low performing hospitals to move out of being penalized. Growing evidence is suggesting that the problem of readmissions goes far beyond the quality of care provided in the hospital or by physicians and includes multiple factors related to patient's conditions and community expectations. In many cases, those hospitals with the highest readmission rates, mired in the penalty, are those that treat poor and vulnerable patients in underserved areas. Unfortunately, the readmissions reduction program does not reward for improvement as the hospital value based purchasing program does, but only measures achievement against peers. There is therefore relatively little incentive for very high or very low performers to spend time addressing this issue. We understand the intent of Congress and the

restrictions on CMS in implementing this requirement but a program that could penalize hospitals for issues that are largely out of their control troubles us greatly.

We hope that Congress and CMS can instead integrate a focus on readmissions into a value-based purchasing program in order to continue to give hospitals a strong incentive to reduce readmissions even further than they have already been reduced. In 2009, the ACC launched a program called “Hospital to Home” – a community initiative to reduce readmissions for heart failure and other cardiovascular diseases. We created this program in collaboration with the Institute for Healthcare Improvement (IHI) because we saw the enormous problems with care during these transition times and the tremendous opportunity for improvement. Participants in this program share success and participate in “challenges” to reduce their readmission rates. Recently, building on the lessons of Hospital to Home, we announce the launch of a patient navigator program that will work with 35 hospitals to reduce readmission rates for patients following myocardial infarction, measuring quality of care using registries that are already in place. We believe this is an incredibly important issue and requires collaboration to address.

Changes to existing measures to accommodate planned readmissions

The ACC strongly supports the CMS changes to the existing readmission measures that will better recognize planned readmissions. The measures previously considered all readmissions to essentially be errors. Patients receiving care for acute events are commonly but not typically readmitted for procedural services – some of these may be planned as a result of their acute events – others may have to occur anyway. The ACC supports the new planned readmission algorithm and appreciates the time taken to make sure this algorithm reflects clinical reality. We are not offering comments on the individual changes to the algorithm for specific procedures. We understand that these issues would be addressed through the measure maintenance process and we will plan to address them through that process. We also support the change that follows from this policy that indicates that if a readmission follows within 30 days of the planned readmission, it will not be counted. We agree with CMS that it is too difficult to determine if this should be tied to the initial admission or the planned readmission. Cases such as this will be very uncommon.

Proposed Expansion of the Applicable Conditions for FY 2015

As CMS states, the ACA required the readmissions penalties to at first be calculated based on rates of readmission for AMI, heart failure, and pneumonia but to be expanded to other conditions soon thereafter. The legislation specifically names patients who received percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) surgery and patients with other vascular conditions as ones whose readmissions should be included, although there is discretion on the part of the Secretary in selecting the conditions.

The ACC supports the CMS proposal to not include PCI readmissions as part of the readmissions penalty program at this time. We are very strongly dedicated to reducing the readmission rate for PCI patients in Medicare. Recently, we have worked with the Yale Center

for Outcomes Research and Evaluation and CMS to calculate a risk-adjusted 30 day PCI readmission measure that will be publicly displayed on Hospital Compare starting in July. This measure is the first step towards a broad public reporting effort on the part of the NCDR in the hospital area. More than 300 hospitals have signed up to be part of this program.

Despite our commitment to reducing these readmissions, we support the CMS proposal to not include the measure in the readmission penalty program at this time. Most importantly, CMS states that PCIs are increasingly being performed in a hospital outpatient setting. We agree that this is the case, with the most recent Medicare data showing that more than one third of PCI cases are performed in the hospital outpatient setting and we expect that shift to continue as technology improves. We hope that in the future we can look at measures from a patient-oriented perspective so that patients who receive PCI in the inpatient and outpatient setting, which are in fact the same place, can be counted as one group for measurement. The ongoing arbitrary distinction between inpatient and outpatient again proves to be problematic in this case. In addition, PCI is not performed in approximately one half of the hospitals in this country and it may be better to focus on measures that cover a broader number of hospitals.

CMS indicates that it will explore the inclusion of CABG readmission in future rulemaking and does not address the readmissions of patients with other vascular conditions as part of this proposed rule. We are unable to offer much comment on this portion of the rule without more information on the readmission rate for these procedures or rationale why they might be included or excluded.

We are generally supportive of the direction of CMS to broaden the patient population for these readmission measures to include patients hospitalized for chronic obstructive pulmonary disorder and those who received hip and knee replacements. There are large volumes of patients who are discharged with these conditions/procedures. The measures that are part of this program must be properly risk adjusted and the program must be closely monitored as there are strong chances for unintended consequences such as avoiding difficult patients or not admitting patients if they return, rather placing them in observation care for a number of days.

Hospital Value-Based Purchasing Program

Proposal to Remove Measures

The ACC does not support the CMS proposal to remove the measure used to measure if primary PCI was received within 90 minutes of hospital arrival (AMI-8a) in 2016 because it is “topped out” with near universal high performance. The fact that this measure is topped-out is an amazing testament to the power of coordinating systems in improving care. In 2006, the College launched a national campaign to reduce “door to balloon” time involving physician, hospitals, ambulances, and other elements of the team responding to AMI. Even we could not have predicted the level of success this program would have as an area where there was once a significant quality gap now shows near universal high performance.

We do not support the removal of this measure because CMS does not propose to monitor performance to ensure that it does not decrease below the current heights, as they have for previous “suspended” measures which contribute to high quality care. We believe this measure is an important sign of high quality care. The vast majority of hospitals performing PCI are measuring their door to balloon time using the Cath-PCI registry and many are participating in the ACTION registry that captures information on all heart attack patients. We believe that CMS should take advantage of this data and continue to monitor the performance on this measure. We urge CMS to continue to pay close attention to these quality measures even if they are removed from the formal program.

We do support the CMS proposal to remove measure HF-1 for Heart Failure Discharge

Instructions. This measure has been retired from the ACC/AHA performance measure list for heart failure patients because the result of the implementation of the measure was improved adherence to providing discharge instructions without strong consideration of the quality of those instructions. We are hopeful that other measures for care transitions for heart failure can be used in the future.

Future Measures for the Efficiency Domain

CMS states that they are considering adding a measure of hospitals’ performances on treating Medicare beneficiaries appropriately as a hospital inpatient or outpatient. We do not support the establishment of a performance measure in this area. There is little difference between patients treated as outpatients and those treated as inpatients. In many cases, they receive the same services in the same building from the same staff. The arbitrary rules continue to cause consternation and confusion. We would likely support a program integrity support that looked at overall patterns rather than individual cases because of these confusing rules. However, we do not believe that there is any element of quality improvement or performance measurement that is part of this and it should not be included as part of the hospital value-based purchasing program.

CMS is also requesting comments on the development of performance measures related to the total use of physician services within a specific specialty at a given hospital stay. Without further information, it is difficult to comment on these ideas. We do believe that there should be shared accountability for the costs of care associated with a patient but we have concerns that a hospital being held responsible for the volume of physician services during a stay could further antagonize relationships between physicians and hospitals. We prefer that efficiency be measured more through appropriate use measures which could clinically demonstrate if a service was needed or not. These measures exist for most major cardiovascular diagnostic services as well as some therapeutic procedures. They are also being adopted in other specialty areas and would be strongly preferable to simple measures of volume.

Hospital Services Furnished under Arrangements

We support the CMS proposal to extend the deadline allowing hospitals to restructure contracts to come into compliance with new restrictions on services that are provided “under arrangement” to 2015. We appreciate that CMS recognizes that many of those organizations that partnered with hospitals under previous rules retain a commitment to high quality care but face difficult and lengthy legal and operational changes. This extension will better allow for a seamless ownership transition that will not limit care.

Policy Proposal on Admissions and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A

Over the years, ACC has expressed continued frustration over the seemingly arbitrary distinction between inpatient and outpatient hospital services. This distinction is a relic of the divided Blue Cross and Blue Shield plans common at the time of the establishment of the Medicare program. While this distinction remains in Medicare, it is long gone in any private insurance market. The role of a hospital in the healthcare environment has changed considerably since that time, with more and more outpatient services being provided and increasing expectation for patients to leave quickly. We understand that the arbitrary distinction between Medicare Part A and Medicare Part B is a complicated issue that must be addressed by Congress rather than CMS, but it remains an ongoing issue for patients, clinicians, and hospitals.

In this year’s rule, CMS proposes that there be a time-based presumption of medical necessity based on the beneficiary’s length of stay. Essentially, patients who remain in the hospital for “two midnights” will be presumed to be inpatients and those who stay less than that will be considered to be outpatients. As CMS states, the percentage of patients in observation status for more than 48 hours has doubled since 2005, which can increase out of pocket expense and reduce availability of post-acute nursing services. CMS had a long established guideline that patients that stay for more than 24 hours would be considered to be inpatients but that guideline has not been supported by decisions of auditors. As we understand it, this time-based rule would provide more guidance than the existing, although medical judgment could be used to justify a shorter admission or a longer observation service. **The ACC supports this proposal because we believe that the use of observation services is a crisis that needs to be addressed with clear guidelines.** We do not believe that hospitals will hold patients far longer than necessary in order to meet the inpatient requirements.

As part of this policy, CMS estimates that there will be approximately \$220 million in additional IPPS payments and CMS proposes to reduce overall payments by this amount to maintain budget neutrality. We believe that such an offset should be equaled on a positive side in the outpatient hospital setting, but that proposed rule is not released until July.

Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

Hospital Compare

CMS has asked for general comments on the use of the Hospital Compare website for public reporting. The ACC has been pleased to get the chance to work with CMS on the public reporting efforts for NCDR. As stated earlier, our first registry measure will be placed on Hospital Compare this summer. We are committed to additional measures from NCDR being reported through this mechanism starting in 2014 and we are thrilled to have CMS as a public reporting partner. We believe that the platform of Hospital Compare offers the best hub for all kinds of measures of hospital performance. The alternative is expecting patients to aggregate information themselves among various specialties of medical care. We are hopeful that CMS will maintain that commitment to full display of quality information that complements the more narrow measurement associated with the hospital value-based purchasing program.

Proposed Removal

As stated in the earlier value-based purchasing section, we support the CMS proposal to remove measure HF-1 for Heart Failure Discharge Instructions from hospital quality reporting.

This measure has been retired from the ACC/AHA performance measure list for heart failure patients because the result of the implementation of the measure was improved adherence to providing discharge instructions without strong consideration of the quality of those instructions. We are hopeful that other measures can be used in the future to measure the important issue of care transitions for heart failure patients.

CMS has proposed the removal of three chart-abstracted process measures (AMI – aspirin at discharge, AMI – statin at discharge, HF – ACEI/ARB for LVSD) because they have achieved near universal high performance. We recognize that the administrative burden associated with chart-abstracted measures limits their numbers. However, we did not see a discussion of the consideration of suspending these measures, rather than removing them, as was previously done for other measures which had topped out. We believe that there should be a consistent plan for monitoring performance when a measure is topped out to ensure that measure performance does not decline following the end of the formal measurement period.

Proposed Refinement to Existing Measures in the Hospital IQR Program

The ACC supports the CMS proposal to incorporate the planned readmission algorithm into the existing 30-day readmission measures. This will improve the measures and ensure that hospitals are not considered to have high readmission rates inappropriately.

Proposed Additional Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

AMI Payment per Episode of Care

CMS has proposed the addition of an additional performance measure of payment per episode of care for patients with acute myocardial infarction. This measure would start measuring the resources used by a patient from the day of admission and conclude after 30 days. **The ACC has**

concerns about the utility of the 30 day AMI payment measure and we do not support the inclusion at this time. We do believe that healthcare providers have a duty to consider overall cost of care but believe that the measure specifications are concerning.

Most importantly, we do not believe that the measure as specified shows a significant variation in care. The specifications provided by the measure developer show that the median 30 day episode payment for a patient with a primary diagnosis of AMI is \$20,152 with a standard deviation of \$1,478. The difference between the 10th percentile and the 90th percentile is around \$3,500. This does not appear to demonstrate a significant care gap. We believe that there are many other episodes, such as stable ischemic heart disease, where the variation in care is much more significant.

This variation may be even less significant than that data suggests because the measure includes the cost of the admission in the calculation. Because a patient with an AMI may be treated medically, with a percutaneous coronary intervention, or with surgery, the payment for the index admission can vary significantly. We have been unable to determine how much of a determinant this is in the cost of care but the fact that the typical payment for a PCI case is approximately \$10,000 tells us that it must be a big factor. If that is the case, the measure will only determine if a patient had surgery or was treated medically. While this may be important information, phrasing it as a cost of care measure confuses the matter. The only large avoidable expense that we believe that AMI patients are typically susceptible to comes from readmissions to the hospital. If the index admission cost and the readmissions cost are the primary contributor to the cost of care, then this measure is neither helpful nor actionable for the providers of care.

CMS is currently working on the development of episode groupers. The groupers are intended to assign specific services to a particular episode such as a patient with AMI. This measure does not appear to be informed by that effort but instead captures all of the costs associated with the patient, regardless of their connection to the episode. We think any measure of episode costs should take advantage of the hard work being performed in creating this episode grouper.

It is very important to measure costs of care but we do not believe that this measure meets the level required to be part of the hospital quality reporting program at this time.

Electronic Clinical Quality Measures

We support the CMS proposal to allow hospitals to electronically report 16 measures starting in the 2014 payment year. As CMS notes, these measure are already required for participation in the hospital EHR meaningful use program and requiring data to be submitted twice is redundant. We also support the cautionary approach of not requiring the data be submitted electronically in 2014 and also not using the data for public reporting in the first year. We agree that there could be data issues associated with a new submission method and believe it best to address those outside of the public reporting sphere. We hope that CMS will continue to

expand efforts to allow for electronic reporting to include registries, which are commonly used for data collection and reporting, in addition to EHRs.

The ACC appreciates the opportunity to comment on the proposed regulations governing inpatient hospitals. We appreciate that CMS takes the time to seriously consider the effect of these new regulations, on patients, clinicians, and hospitals. If you have any questions, please contact Brian Whitman at bwhitman@acc.org or (202) 375-6396.

Sincerely,

A handwritten signature in black ink that reads "John G. Harold MD". The signature is written in a cursive, slightly slanted style. The "MD" is written in a larger, bolder font than the rest of the name.

John Gordon Harold, MD, MACC, MACP, FESC, FCCP, FAHA
President