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September 2, 2008

Mr. Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8011  
Baltimore, MD 21244-8018

ATTENTION: CMS-1404-P

Dear Mr. Weems:

The American College of Cardiology (ACC) is pleased to offer our comments on the notice of proposed rulemaking (CMS-1404-P) entitled: **“Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates** as published in the *Federal Register* on July 18, 2008 *Federal Register*, 73 Fed. Reg. 41416 (“the Proposed Rule”).

The ACC is a 36,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair payment policies for all providers are a critical component of adequate access to care. We offer the following comments in support of that goal.

#### Composite APCs

CMS proposes new five new composite APCs for imaging services based on the families of codes used for the multiple imaging procedure payment reduction policy under the Medicare Physician Fee Schedule. The proposed imaging composite APCs are:

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- Ultrasound
- Computed tomography and computed tomographic angiography without contrast
- Computed tomography and computed tomographic angiography with contrast
- Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) without contrast
- Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) with contrast

Composite APCs for a variety of non-imaging cardiology services were first introduced in the proposed rule for the CY 2008 HOPPS. The ACC at that time urged CMS to proceed with caution regarding the application of this methodology. Any further development of composite APCs should be accompanied by a clear, transparent process and data for identifying and calculating future composite APCs. Additionally, it is important that composite APCs are designed in a manner that sufficiently accounts for the resources associated with performing the common combinations of services. We are concerned that CMS is expanding the composite APC concept before adequate data are available to determine whether the methodology used to establish the existing composite APCs has resulted in accurate payments. We oppose implementation of the proposed composite APCs and strongly encourage CMS to evaluate the impact of the existing composite APCs before proposing a further expansion of this approach.

### **Diagnostic and Therapeutic Radiopharmaceuticals**

The ACC supports CMS's proposal to reimburse for separately payable therapeutic radiopharmaceuticals under the standard drug payment method, based on manufacturer voluntary reporting of average sales price (ASP) +4%. CMS proposes to determine payment based on the mean costs of the therapeutic radiopharmaceuticals, derived from hospital claims data, when ASP data is not provided or unavailable. Providing separate, equitable reimbursement for both diagnostic and therapeutic radiopharmaceuticals is essential to ensuring access to nuclear cardiology procedures and treatments for all Medicare beneficiaries. We urge CMS to work with all affected stakeholders – physicians, hospitals, and manufacturers – to establish appropriate policies and accurate pricing methodologies.

As noted in previous comments, the ACC disagrees with CMS's decision to classify radiopharmaceuticals as "supplies" rather than drugs. Radiopharmaceuticals are unique drugs that are integral to every nuclear medicine procedure. Radiopharmaceuticals are regulated as drugs by both the FDA and NRC, and the Medicare HOPPS statute consistently recognizes all radiopharmaceuticals – diagnostic and therapeutic – as "specified covered outpatient drugs." We believe that bundling diagnostic radiopharmaceuticals with the procedure APC payment based on this erroneous classification is unjustified.

While the passage of H.R. 6331, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), mandates an ongoing payment for therapeutic

radiopharmaceuticals in the hospital outpatient setting based on the individual hospital's charges reduced to cost for 2009, ACC is hopeful that CMS will move forward with its proposal to reimburse for therapeutic radiopharmaceuticals based on ASP +4% in 2010 and beyond. ACC is also very hopeful that CMS will work with radiopharmaceutical manufacturers, nuclear pharmacies and other interested parties in creating a similar reimbursement strategy for diagnostic radiopharmaceuticals for 2010 and beyond.

The ACC supports CMS's proposal to grant new diagnostic and therapeutic radiopharmaceuticals pass-through status and provide payment for these products based on ASP methodology, when available, as an intermediate step. We note that the add-on percentage payment for radiopharmaceuticals should be adequate to account for the high overhead costs of preparing, administering and disposing of the radioactive product. Although the ACC is pleased that CMS has granted pass-through status for new diagnostic and therapeutic radiopharmaceuticals, we encourage CMS to extend that status for a full 3-year time frame, rather than only 2 years. Hospitals are often slow to update their charge masters and code correctly for new products, resulting in claims data that is volatile, insufficient and inaccurate.

### **Intravascular ultrasound and intracardiac echocardiography**

CMS has overturned the recommendation of the APC Panel to reinstate separate payment for several procedures packaged into diagnostic cardiac catheterization APCs in 2008. These include:

- Intravascular ultrasound (IVUS - CPT 92978, 92979 & 37250, 37251)
- intracardiac echocardiography (ICE - CPT 93662)

The ACC continues to oppose the packaging of these services. The procedures included in this section offer significant clinical benefits for patients and can even reduce net Medicare expenditures. By providing additional clinical information to cardiologists, these procedures frequently allow physicians to decide against performing an intervention on a patient. Additionally, when an intervention is performed, the additional clinical information obtained from the add-on procedures listed above is used to assure the most appropriate size and placement of a stent. Optimal sizing and placement of stents is clearly linked to improved patient outcomes and a reduced need for subsequent procedures.

Additionally, we note that hospitals incur significant capital and operational costs to provide these options to patients undergoing cardiovascular interventions and that, even with current reimbursement for these procedures, many hospitals do not provide these diagnostic options. The APC Panel noted in March 2008 and again in August 2008 that these procedures are performed infrequently and the costs are not adequately captured with the primary procedures with which they are now packaged. We believe that although these services are only performed in conjunction with another procedure, they are not incidental or minor. Significant separate resources are required to provide these services. By eliminating separate facility reimbursement for these clinical options, we are

concerned that CMS could be limiting treatment options for Medicare beneficiaries. We urge CMS to implement the recommendations of the APC and reinstate separate reimbursement for intravascular ultrasound and intracardiac echocardiography.

### **Diagnostic Myocardial Positron Emission Tomography (PET) – APC 0307**

For 2009, CMS has proposed a reimbursement rate of \$1,143 for APC 0307, Myocardial Positron Emission Tomography (PET) Imaging – multiple and single studies – compared to the \$1,400 reimbursement rate in 2008, a decrease of 18 percent. The bundled payment rates include the cost of the high-priced diagnostic radiopharmaceuticals that are used in performing these procedures. The ACC disagrees with the proposed reimbursement rate as unreasonably low; we believe this proposed payment rate is based on inadequate data from fewer than 2,800 claims. OPFS reimbursement rates for cardiac PET have shown significant volatility over the past few years. The current limited CMS hospital charge data on this technology is inadequate and flawed. The ACC urges CMS to accept external data (the MPFS pricing has been much more stable over this period) when setting payment rates for Myocardial PET. In the absence of external data and in an effort to provide greater stability, the ACC recommends that for CY 2009 CMS freeze the payment rate for Myocardial PET at the current CY 2008 APC payment rate of \$1,400.

### **Fetal echocardiography APC 0265 and 0266**

CMS has assigned CPT codes 76825 (Fetal echocardiography) and 76826 (Fetal echocardiography; follow-up or repeat) to APCs for general ultrasound services rather than to APCs for echocardiography services. CPT 76825 is assigned to APC 0266, which includes procedures such as CP 76536 (Ultrasound of the head and neck) and 76818 (Fetal biophysical profile with non-stress test). CPT 76826 is assigned to APC 0265, which includes procedures such as 76604 (Ultrasound, chest) and 76815 (Obstetric ultrasound, limited). The resources required to perform fetal echocardiography services differ substantially from those required for the other services included in APCs 0265 and 0266. Fetal echocardiography is performed by specially trained cardiac sonographers and requires different equipment than the ultrasound equipment used for the other procedures in these APCs. For these reasons, the ACC recommends that CMS reassign CPT code 76825 to APC 0269 (Level II Echocardiograph without contrast except transesophageal). Similarly, we recommend that CMS reassign 76826 to APC 0697 (Level I echocardiogram without contrast except transesophageal).

### **Insertion/Replacement of Pacemaker Leads and/or Electrodes and 0418 Insertion of Left Ventricular Pacing Electrode (APCs 0106 and 0418)**

The ACC is deeply concerned about the proposed payment rates for APCs 0106 (Insertion/Replacement of Pacemaker Leads and/or Electrodes) and 0418 (Insertion of Left Ventricular Pacing Electrode). The proposed rates represent decreases of 26 percent and 47 percent, respectively. We believe that reductions of this magnitude may make it

financially prohibitive for institutions to offer lead placement and cardiac resynchronization therapy (CRT) device implants to patients in need of these services.

The Heart Rhythm Society has recommended several options for stabilizing the OPPS payment rates for these services in 2009. These options include:

- limiting the reduction in payment rate that any device-dependent APC may experience in a single year to 10 percent;
- further analyzing claims data for device-dependent APCs with rates calculated to drop more than 10 percent to identify areas that may inaccurately contribute towards the reduction; or
- creating new composite APCs for CRT procedures.

The ACC strongly urges CMS to give careful consideration to the Heart Rhythm Society's recommendations and take the necessary to actions to ensure adequate access to lead placement and CRT for Medicare beneficiaries.

### **Cardiac Rehabilitation – Non-standard Cost Centers**

CMS has requested comments on the creation of new nonstandard cost centers for cardiac rehabilitation services. The ACC notes with concern that APC payment rates for cardiac rehabilitation have declined over the past several years. We believe that establishing fair reimbursement rates for cardiac rehabilitation is crucial to ensuring availability of these important services for Medicare beneficiaries. A CMS-commissioned report from the Research Triangle Institute referenced in the Proposed Rule includes several recommendations for technical changes to the methodology for calculating APC payment rates for cardiac rehabilitation. The ACC urges CMS to give careful consideration to those recommendations and to work collaboratively with affected stakeholders to make all necessary and appropriate changes.

### **Healthcare-Associated Conditions**

CMS has requested comments on the possibility of broadening the concept of the hospital acquired payment provisions of the inpatient prospective payment system to the outpatient prospective payment system. The ACC is strongly committed to quality improvement and we support the concept of establishing appropriate financial incentives as a tool for achieving quality improvement goals. We recognize that in implementing the Hospital Acquired Conditions (HAC) initiative, CMS is carrying out its statutory obligation under the Deficit Reduction Act (DRA) of 2005. Nevertheless, the College has serious concerns about both the approach to reducing the incidence of preventable hospital acquired conditions mandated by the DRA and the manner in which CMS is implementing its statutory obligations.

The College has a fundamental disagreement with quality improvement strategies that rely on only negative reinforcement, such as non-payment for hospital acquired conditions. We believe the HAC initiative is seriously flawed for a number of reasons:

- Determining and documenting that one of the selected HACs was present on admission is not always possible and creates a burden for hospitals.
- There is no provision for risk adjustment. Some patients are at substantially elevated risk for a number of the HACs.
- Non-payment for HAC could encourage hospitals to avoid patients at higher risk of complications and creates an incentive for a hospital to transfer a patient who develops complications.
- There are no provisions to reinvest savings in the system to further improve quality of care.

The ACC believes that setting ambitious goals can challenge health care providers to achieve quality improvement goals they may not have thought possible. However, those goals must be realistic and reasonably achievable. Moreover, providers need practical tools that help them take steps toward achievement of the goal. In the absence of these elements, the HAC initiative is simply a punitive payment policy, not a concrete strategy for improving the quality of hospital care provided to Medicare beneficiaries.

We urge CMS to halt any expansion of this initiative beyond compliance with the DRA mandate to identify two HACs for non-payment beginning October 1, 2008. Any proposed expansion should be delayed until CMS has conducted a thorough evaluation. For example, CMS should assess the impact of the HAC initiative on the incidence of the selected HACs, the administrative burden placed on providers and CMS, and the accuracy of present on admission (POA) coding. In addition, we urge CMS to develop effective risk adjustment techniques to ensure that providers who care for high risk patients are not unfairly penalized.

The ACC was pleased that CMS did not finalize its proposal included in the proposed rule for the Inpatient Hospital Prospective Payment System to expand the list of HACs. The ACC had opposed this proposal because the proposed HACs did not fulfill the statutory requirement of being reasonably preventable. We believe that these conditions should not be characterized as “never events.” Rather, they are known complications which can be minimized with proper care. These conditions cannot always be prevented, even in the best circumstances. A blanket policy of non-payment for the costs associated with caring for patients who experience such complications during a hospital stay or in any other site of service is unreasonable.

CMS has requested comments on alternative approaches to reducing the occurrence of preventable hospital acquired or healthcare-associated conditions. The ACC recommends that CMS explore alternatives that would use a data-driven approach to establishing benchmark and best practice complication rates for selected HACs. CMS could then set payment rates based on an average complication rate and provide evidence-based tools to

help hospitals work toward a best practice complication rate. Those hospitals whose complication rates exceeded the average would bear the costs of treating those complications, while those with better than average performance would be rewarded. As performance improved over time, payment rates would be adjusted to reflect lower complication rates. Data registries such as the NCDR™ CathPCI and ICD Registries would be an excellent source of data on complication rates.

CMS has now requested comments on possible application of the concept underlying the HAC initiative in other settings. CMS should not consider expansion of the HAC approach to other care settings until the initiative has been thoroughly evaluated within the IPPS program.

### **Quality Reporting Requirements**

For a hospital to receive the full outpatient update payment factor in 2010, CMS proposes reporting on four new imaging efficiency measures, along with continued reporting on the seven quality measures in place during the initial measurement reporting implementation of the Hospital Outpatient Quality Data Reporting Program (HOPQRDP) in 2008.

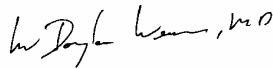
The ACC opposes implementation of the four new imaging measures proposed for reporting in 2009 to be included in the 2010 payment year. The National Quality Forum (NQF) has not endorsed these measures, nor have they been considered for adoption by the Hospital Quality Alliance (HQA). We also recommend that CMS solicit input from organizations such as the PCPI. Moreover, measures that relate to physician performance in the hospital outpatient setting should be aligned with physician measures utilized in other CMS quality programs, such as the PQRI.

The Proposed Rule Further, since the imaging measures are still in the developmental process, CMS was not able to propose such critical information about the proposed measures, such as measure specifications, an appropriate rationale for each measure, discussion of the evidence underlying the measures, nor an explanation of the expected value of putting the measure into place. When proposing new measures for public comment, such as the imaging efficiency measures, it is critical that CMS provide essential information, including measure specifications and other material information, as discussed above, so that the public is able to make informed comments. CMS' current proposal with regard to these imaging measures is unclear and thus we are unable to provide meaningful comment on them at this time.

Accordingly, we urge CMS to not adopt the four imaging measures at this time and to re-evaluate the measures at such time as essential measure specification, NQF endorsement, and HQA consideration can be accomplished.

We appreciate your attention to this letter, and remain eager to assist you and your staff as it considers whether to finalize these proposed changes to the 2008 Medicare Hospital Outpatient Prospective Payment System rule. If you have any questions, please contact Rebecca Kelly, Director – Regulatory Affairs at 202.375.6398, or by e-mail at [rkelly@acc.org](mailto:rkelly@acc.org).

Sincerely,



W. Douglas Weaver, M.D., F.A.C.C.  
President

cc: Jack Lewin, M.D.  
Chief Executive Officer