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Thomas E. Arend, Jr.

October 10, 2006

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Dear Ms. Norwalk:

The American College of Cardiology (ACC) is a 30,000 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.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (CMS 1321-P)** published in the *Federal Register* on August 22, 2006. 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 physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

DRA Proposals

Section 5102 Multiple imaging procedures

The ACC supports CMS's proposal to maintain the payment reduction for the technical component of certain multiple imaging procedures at 25 percent for the second and any subsequent procedures instead of the previously proposed 50 percent. As we noted in comments submitted previously, we recognize that physician practices may achieve some savings in practice expenses when multiple imaging procedures are performed on contiguous body parts during

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the same patient care session. However, the ACC disagreed that the data on direct practice expense inputs supported a reduction of 50 percent. We are pleased that CMS has responded favorably.

As a result of the savings from the multiple imaging procedure payment reduction, CMS increased the 2006 practice expense RVUs by 0.3 percent. The proposed rule notes that this increase will be removed from the 2007 practice expense RVUs to comply with the Deficit Reduction Act (DRA) requirement that the multiple imaging procedure payment reduction be exempted from the budget neutrality requirement. The ACC understands that CMS is merely complying with the statute in making this change. We must note, however, our strong objection to singling out one type of physician service to achieve savings in overall Medicare physician payments.

Section 5102 Limit on payment for technical component of imaging procedures

The ACC strongly opposes the DRA provision limiting payment for the technical component of imaging services to the lesser of the payment amount under the Medicare physician fee schedule or the payment amount under the hospital outpatient prospective payment system (OPPS). We object to the process through which it was enacted without full discussion and public debate, to the precedent it sets of targeting imaging services to achieve savings in physician payment, and to the invalid comparison it makes between two fundamentally different payment systems. We recognize, nevertheless, that CMS must implement the statutory requirement. ACC's comments on several aspects CMS's proposal for implementing this DRA provision follow.

Definition of imaging services

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the OPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, CMS proposes to define imaging as "services provid[ing] visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." We believe this proposed definition is overly broad and, theoretically, could even apply to open surgical techniques. We recommend the following definition of imaging for purposes of implementing the DRA:

Medical Imaging uses noninvasive techniques to view all parts of the body and thereby diagnose an array of medical conditions. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide minimally invasive diagnostic therapeutic procedural interventions such as percutaneous angioplasty, hepatic embolization, or cardiac catheterization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the

absence of minimally invasive diagnostic procedures and interventions; and without this type of imaging only open surgical procedures would be possible.

The ACC does not believe that this type of real-time, imaging guidance was the intended focus of the DRA imaging reimbursement cap. These imaging guidance services are differentiated within CPT by the inclusion of the nomenclature "radiological supervision and interpretation" or "imaging supervision and interpretation" within the code descriptors. We believe that these services should not be subject to the DRA reimbursement cap.

Services included in Addendum F

The preamble to the proposed rule states "We excluded all HCPCS codes for imaging services that are not separately paid under the OPSS since there would be no corresponding OPSS payment to serve as a TC cap." However, Addendum F includes 93555 and 93556 (Imaging, cardiac catheterization). Under OPSS imaging guidance is bundled into the payment for cardiac catheterization, so there is no separate OPSS payment corresponding to either 93555 or 93556. We believe CMS included these two codes in error and we urge that they be removed from Addendum F.

The ACC also recommends that CMS exclude Category III CPT codes from the list of procedures subject to the DRA cap on payments for the technical component of imaging services. By definition, Category III codes describe emerging technology. Thus, no RVUs have been assigned to reflect costs in the physician office setting and OPSS payment rates do not reflect the costs of providing these procedures in the hospital outpatient setting. Therefore, the ACC believes it is inappropriate to apply the DRA payment limitation to emerging technology services currently identified by Category III CPT codes.

Services subject to both the DRA cap and the multiple procedure payment reduction

The ACC supports CMS's decision to apply the multiple procedure payment reduction first for those services subject to both the cap on the technical component payment and the multiple imaging procedure payment reduction.

Resource Based Practice Expense RVU Proposals for 2007

The ACC's comments on the June 29, 2006 proposed rule included a discussion of our concerns about the significant decreases in practice expense RVUs proposed for cardiac catheterization services performed in the non-facility setting (CPT 93510 - 93533). As we noted, we believe that the magnitude of the proposed cuts for these services reflects, in large measure, weaknesses in data used for establishing both the direct and indirect cost portions of the RVUs.

In the August proposed rule, CMS proposed carrier pricing for these codes. We agree that the data problems affecting these codes are so significant that even the proposed first year

transition values are probably inappropriate and could adversely affect patient access. We believe, though, that carrier pricing is not the most appropriate strategy for establishing 2007 values. It is our understanding that other commenters will be submitting to CMS data on direct expenses. The ACC has not yet reviewed these data. We plan to work closely with all affected stakeholders to review existing data, gather any additional data needed, and request prompt review by the PERC. Until the ACC and the PERC can complete this review, we recommend that CMS use the 2006 non-facility RVUs for CPT 93510 - 93533 as interim values for 2007.

Cardiac monitoring

The ACC remains concerned that the significantly reduced practice expense RVUs proposed for remote cardiac monitoring services could threaten patient access to these important services. We are pleased that CMS has requested additional practice expense data for these procedures. We note that CPT 93236 (24 hour electrocardiographic monitoring) should be added to the list. The ACC concurs with CMS’s assessment that remote cardiac monitoring services do not fit the typical physician service model for purposes of developing direct practice expense inputs. Consequently, the current direct practice expense inputs do not capture all practice expenses required to provide remote cardiac monitoring services. We look forward to working with CMS and remote cardiac monitoring services providers to gather and review the necessary data.

Supply and equipment information

Tables 1 and 2 in the preamble to the proposed rule identified several supply and equipment items for which CMS needs of current price information. Following is ACC’s response to this request.

Table 1 Supply items needing specialty input for pricing			
Code	Description	New price	Source
SK 105	Blood pressure recording form	NA	
This item can be deleted. The ambulatory blood pressure monitoring system for which we are providing new price information generates the form, so separate pricing is not necessary.			
SD 140	Pressure bag	\$95.00 per 5 unit box	McKesson
SD 213	Tubing, sterile, non-vented (fluid administration)	\$47.46 per 50 unit box	McKesson
Table 2 Equipment items needing specialty input for pricing			
Code	Description	New price	Source
EQ 269	Ambulatory blood pressure monitor	\$1920	Tiba Medical
EQ 008	ECG signal averaging system	\$17,900	GE
System includes ECG cart (\$12,500), software for late potential QRS (\$3,200), and software for P-wave measurement which is less common (\$2,200).			

We have forwarded this information, along with documentation of the prices to the responsible CMS staff.

PLI RVUs

Currently, CMS assigns professional liability insurance (PLI) RVUs to the professional and technical components of codes by allocating the PLI RVUs for the global code on the basis of the division of practice expense RVUs between the two components. The ACC believes that in the case of imaging services, this approach results in PLI RVUs that do not accurately reflect the relative professional liability costs associated with the professional and technical components. Although the technical performance of an imaging service does entail some professional liability risk, the liability risk associated with the physician interpretation of the imaging service is much greater. We urge CMS to develop a more accurate method for distributing the PLI RVUS between professional and technical components. Development of such a method may not be accomplished quickly. In the short term, therefore, we recommend that CMS reverse the current assignment of PLI RVUs between technical and professional components.

Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

The ACC has strongly and consistently supported efforts to eliminate or severely reduce opportunities for fraud and abuse in the Medicare program. The proposed rule revisions to the physician self-referral rules appear to target apparent abuses within pathology services. The ACC, therefore, recommends that CMS strictly limit the application of these changes—if adopted—to the field of pathology at the present time.

We believe this is the most appropriate course of action for CMS to pursue at this time, as it is our understanding that the medical societies representing pathologists initiated the development of these proposed rule changes with the agency out of concern for the specific practices emerging in that field (i.e. “pod-labs.”). Further, we also understand that the proposed revisions are the product of a collaborative effort between CMS and those pathologist groups, and that the revisions generally meet with the pathology groups’ approval. The ACC commends CMS for taking this collaborative approach to rulemaking.

As noted by the preamble itself, CMS is seeking comments on whether the proposed changes should apply strictly to pathology services, or if they should also extend to diagnostic imaging and other services beyond pathology (71 Fed. Reg. 49056; August 22, 2006). At the present time, we believe that the impact of these proposed regulations on diagnostic imaging and other non-pathology services cannot be accurately studied within the relatively short timeframe afforded by the comment period for the proposed 2007 Medicare Physician Fee Schedule. Among possible ACC concerns requiring additional study:

- The proposed conditions of permissible billing for technical and/or professional components (TC/PC, respectively) of testing services may significantly interfere

- with physician group practices' flexibility in legitimately contracting with independent physicians, thereby potentially increasing costs to the Medicare program; and
- The proposed changes to the reassignment rules, along with the modifications to the "centralized building" requirements may also significantly impede the incorporation of certain diagnostic imaging services into (non-radiology) physician group practice settings—potentially closing opportunities to reduce costs and inefficiencies in the delivery of these critical services to Medicare beneficiaries.

To ensure that such rules with potentially wide-ranging and disruptive effects on the quality of care are adequately studied prior to adoption, the ACC reiterates its strong recommendation that CMS limit the application of these proposed revisions strictly to pathology services (e.g. pod-labs, etc.), and that the agency engage with the ACC and other stakeholder groups to study and develop solutions to potential fraud and abuse concerns in other areas of care. The ACC remains eager to work with CMS on such an endeavor.

Independent Diagnostic Testing Facility (IDTF) Issues

With regard to the application of the proposed standards to IDTFs, the ACC recommends that CMS carefully evaluate whether, as currently written, they should apply uniformly to the diverse array of services provided by these entities. We also encourage CMS to consider accreditation status as an alternative mechanism for compliance with the proposed standards. Specifically, we suggest that entities that have been accredited by a nationally recognized accreditation body, such as the Intersocietal Accreditation Commission, could be deemed to be in compliance with Medicare's IDTF standards. In the alternative, the ACC urges CMS to work with IDTFs and other stakeholders to ensure that the proposed standards properly target questionable practices while not impeding the provision of legitimate and beneficial services for Medicare beneficiaries.

Promoting Effective Use of Health Information Technology (HIT)

The ACC strongly supports the incorporation of health information technology (HIT) into the practice of medicine and throughout the health care industry in general, out of recognition for both the potentially significant improvements to the quality of care provided to patients and the administrative cost savings involved.

We agree with CMS' conclusion that the selection and promotion of voluntary data and systems standards is key to achieving effective HIT implementation among providers and payers. It is critical to the success of HIT implementation that the process for developing standards must include thorough consideration by HHS/CMS of the input from all stakeholders.


For these reasons, the ACC recommends that CMS continue to collaborate with all stakeholders in the process of developing HIT standards and implementation timeframes, only establishing and promoting such standards after carefully considering such input.

Health Care Information Transparency Initiative

The ACC shares with CMS concerns regarding rapidly escalating health care costs and expenditures, and recognizes the need to implement reforms aimed at introducing cost efficiencies while also improving the quality of care provided. While “transparency” of costs and prices may indeed have an important role to play in helping to curb the growth of health care costs, we have concerns regarding possible misrepresentations or misinterpretations of such data, particularly in the latter example by patients. To ensure complete and accurate data is assembled for these consumer resources, we urge CMS not to rely exclusively on claims data, and instead incorporate information from a variety of sources.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS’ continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC’s Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org with any questions.

Sincerely,

A handwritten signature in cursive script that reads "Steven E. Nissen".

Steven E. Nissen, MD, FACC
President