July 3, 2002

Thomas Scully, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
CMS–1203–P
P.O. Box 8010
Baltimore, MD 21244–1850

RE: Medicare Program; Proposed Rule - Hospital Inpatient Prospective Payment Systems and 2003 FY rates

Dear Mr. Scully:

The American College of Cardiology (ACC) is a 29,000 member nonprofit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC appreciates the opportunity to submit our comments on the proposed changes to the 2003 hospital inpatient prospective payment system, as published in the May 9, 2002 *Federal Register*.

EMTALA
The ACC is pleased that CMS proposes to make significant improvements in the EMTALA regulations. We have offered our support for these changes and constructive recommendations via a joint letter with many other physician organizations, including the American Medical Association. We also appreciate CMS accepting the recommendations of Secretary Thompson's Regulatory Reform Workgroup, chaired by cardiologist Douglas Wood, MD, FACC, on necessary changes to EMTALA.

Heart Assist Systems
The ACC supports CMS' proposal to remove circulatory support devices, also known as heart assist systems or left ventricular assist devices (LVADs), from DRGs 104 and 105. According to CMS' data, the average charge for LVADs is approximately $36,000 and $85,000 higher than the average charges for all other cases in those two DRGs, but accounts for only 1.3%

and .5% of the overall volume, respectively. It appears both clinically and economically reasonable to remove these cases and create a separate DRG as proposed (DRG 525 for Heart Assist System Implants). There will also be little effect on payment for DRGs 104 and 105 by the removal of LVAD cases due to their low volume.

Radioactive Element Implant
CMS has determined that radioactive element implant (code 92.27) does not always need to accompany cases involving a percutaneous cardiovascular procedure and intravascular radiation treatment and can stand alone in other types of cases. The ACC supports CMS' proposal to reassign radioactive element implant from DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) to DRG 120 (Other Circulatory System O.R. Procedures) in cases where DRG 517 (Percutaneous Cardiovascular Procedure without Acute Myocardial Infarction with Coronary Artery Stent Implant) is not the appropriate assignment. We feel this is a clinically appropriate reassignment.

Drug-Eluting Stents
Drug-eluting stents have the potential to significantly improve the care of patients with cardiovascular disease. We encourage CMS to develop payment systems that will provide Medicare beneficiaries with rapid access to these devices as soon as it is medically appropriate to do so. Reduced restenosis will not only improve patient outcomes, but may also reduce Medicare's costs through reduced numbers of repeat procedures and a reduction in the number of more invasive procedures. These savings of course may be offset by the higher cost of the devices and by lowering the risk threshold at which the decision to place a stent is made. ACC recommends that CMS develop a payment structure that will not financially penalize facilities when drug- eluting stents are implanted in Medicare beneficiaries.

Cardiac Resynchronization Therapy (CRT)
Five new ICD-9 procedure codes were established for CRT ICD and pacemaker procedures effective October 2002. Both the ACC and the North American Society of Pacing and Electrophysiology (NASPE) oppose CMS' proposal to assign cardiac resynchronization ICD procedures with EP study to DRG 514 (ICD System Implant with EP Study or Cardiac Catheterization) and CRT-ICD procedures without EP study or cardiac catheterization to DRG 515 (ICD System Implant w/o EP Study or Cardiac Catheterization). Cardiac resynchronization pacemaker procedures would be assigned to DRG 115 (Pacemaker Implant with AMI/HF).

We believe the proposed CMS assignment to either of the conventional ICD DRGs, 514 or 515, will result in inadequate payment given the higher cost associated with treating these heart failure patients, the additional resources in placing the left ventricular lead and the incremental cost of the CRT system. There is also considerably higher time and cost in treating heart failure patients compared to a typical pacemaker and ICD patient, including the procedure time and the patient's length of stay. We are concerned about

restricted patient access if hospitals are forced to absorb the costs of this new therapy due to low reimbursement.

Therefore, ACC and NASPE recommend that CMS assign all CRT pacemaker cases to DRG 515 and CRT-ICD cases to DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures w/Cardiac Catheterization). At a minimum, we recommend CMS assign all CRT-ICD procedures to DRG 514 (even those without an electrophysiology study).

CONCLUSION

The ACC appreciates this opportunity to comment on CMS' proposed hospital inpatient payment policies for 2003. If we can provide any further information about our comments, please contact Wayne Powell, ACC Director, Regulatory and Legal Affairs at (301) 493-2337.

Sincerely,

W. Bruce Fye, MD, MA, FACC
President

cc: Christine McEntee
Karen Collishaw

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