July 2, 2002

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1203-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates, Proposed Rule, CMS –1203 - P

The North American Society of Pacing and Electrophysiology (NASPE) is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. NASPE's mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. NASPE's 3,500 members are physicians, scientists and their support personnel who implant pacemakers and implantable cardioverter defibrillators (ICDs) in patients who require these life-saving devices. NASPE members have also been at the forefront treating congestive heart failure patients with cardiac resynchronization therapy (CRT). Your proposal to assign CRT to DRGs 115, 514 and 515 may have a serious impact on the way these cardiac procedures are provided to patients in our nation's medical centers. NASPE recommends the Center for Medicaid and Medicare Services (CMS) re-assign CRT-pacemaker procedures to DRG 515 (ICD system implant w/o EP study or cardiac cath) and CRT-ICD procedures to DRG 104 (cardiac valve and other major cardiothoracic procedures w/cardiac cath).

NASPE appreciates the opportunity to comment on the CMS Notice of Proposed Rulemaking (NPRM) in the Medicare Hospital Inpatient Prospective Payment System for FY 2003 published in the May 9, 2002, *Federal Register*. Our comments focus on the proposed payment rates for procedures using implantable cardioverter defibrillators (ICDs) and pacemakers and the DRG assignment for CRT.

Proposed Changes to DRG Relative Weights for Pacemaker and ICDs

NASPE is pleased to see modest increase in the DRG weights for many pacemaker and ICD DRGs. NASPE continues to receive feedback from our membership that the cost of providing these services to patients is outpacing the level of reimbursement the hospital receives. We understand these DRG changes are based on aggregate data hospitals submit to CMS and are contained in CMS's MedPar database. NASPE is pleased to see the DRGs beginning to reflect the true costs of providing these services. The device costs for pacemaker and ICD procedures continues to often reach or exceed the total DRG payment with the other costs of the procedure (cath/electrophysiology lab, personnel, hospital room and other equipment) left unpaid.

Cardiac Resynchronization Therapy

NASPE welcomes the new ICD-9 codes created to report different aspects of cardiac resynchronization therapy (CRT). Five new ICD-9 procedure codes were established for CRT ICD and pacemaker procedures effective October 2002. Establishment of these codes will permit more accurate tracking of the cost of the procedures and assignment to more adequately paying DRGs in the future. However, CMS has proposed using existing DRGs to pay for cardiac resynchronization therapy (CRT). CMS proposes to assign CRT-ICD procedures with EP study to DRGs 514 (ICD system implant with EP study or cardiac cath) and CRT-ICD procedures w/o EP study or cardiac cath to 515 (ICD system implant w/o EP study or cardiac cath). Cardiac resynchronization pacemaker procedures would be assigned to DRGs 115 (Pacemaker implant with AMI/HF). CMS has indicated that it is soliciting comments on these DRG

assignments and will carefully consider any relevant evidence on the clinical efficacy and cost of this technology.

Firstly, NASPE would like to comment on the clinical efficacy of this treatment for congestive heart failure that has been established in the medical literature. For congestive heart failure patients, this technology provides a breakthrough in the treatment of these patients by improving exercise performance, quality of life measures, and heart failure symptoms while decreasing hospitalizations related to heart failure. (Abraham, et al, N. Engl J Med 2002; 346:1902-5. Auricchio et al, J Am Coll Cardiol 2002: 39: 2026-33, Nelson et al, Circulation 2001: 103: 476. Leon et al, J Am Coll Cardiol 2002: 39: 1258-63.)

- For CRT ICD cases, the proposed CMS assignment to either of the conventional ICD DRGs, 514 or 515, would result in inadequate payment given the higher cost of treating heart failure patients and the additional resources associated with placement of the left ventricular lead and the incremental cost of the CRT system.
- There is considerable more time and cost expended to treat heart failure patients compared to typical pacemaker and ICD patients including; significantly increased procedure time to place the left ventricular lead in the coronary sinus in addition to the placement of the pacemaker or ICD; additional length of stay for heart failure patients due to their overall reduced health status; and the increased costs of these devices to the hospital. NASPE is concerned that this proposed DRG placement will lead to underpayment for this new technology, forcing hospitals to absorb the costs of this new therapy and potentially restricting patient access.
- NASPE recommends CMS assign all CRT pacemaker cases to DRG 515 (ICD system implant w/o cardiac cath/EP study) and CRT-ICD cases to DRG 104 (cardiac valve and other major cardiothoracic procedures w/cardiac cath). At a minimum, NASPE recommends CMS assign all CRT-ICD procedures, even those without an electrophysiology study, to DRG 514 (ICD system implant w/EP study/cardiac cath).

NASPE members' primary goal is to improve cardiovascular patient care through the diagnosis and treatment of patients with cardiac arrhythmias. NASPE is concerned that these proposed DRG assignments for cardiac resynchronization therapy will be an incentive for hospitals to discourage the use of this advanced device therapy for heart failure patients.

If NASPE can provide any further information or assistance to you or your staff, please contact Amy Melnick, NASPE's Director of Government Relations at 202-416-1871 or amelnick@naspe.org. We look forward to working with you to provide Medicare beneficiaries continued access to these critical cardiovascular devices.

Sincerely,

Mark H. Schoenfeld, MD
President
NASPE