



Heart Rhythm Society



VIA ELECTRONIC MAIL

September 14, 2007

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: CMS-1517-F Medicare Program; Revised Payment System Policies for Services
Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008

Dear Administrator Weems:

On behalf of the Heart Rhythm Society (HRS) and the American College of Cardiology (ACC), please accept the following comments on Section III (Covered Surgical Procedures Paid in ASCs On or After January 1, 2008) of the final rule published on August 2, 2007 (72 FR 42470), which finalizes revisions to the Medicare ambulatory surgical center (ASC) payment system for 2008.

HRS and ACC appreciate the consideration and effort required by CMS to develop the new ASC payment system; we are disappointed that CMS' did not adopt its proposal to establish a new site of service volume criterion under which any procedure performed 80% or more of the time in the hospital inpatient setting would be excluded from payment in an ASC facility. Medicare utilization has always been an important data source used to determine policy changes for all of CMS' prospective payment systems. We believe the inpatient site of service restriction, in regards to certain electrophysiology surgical procedures, has proven to be a reliable patient safety safeguard thus far. CMS' decision to disregard inpatient utilization as criteria for selecting services for ASC eligibility leads us to believe that ensuring the safety of Medicare beneficiaries was not the primary goal in revising the payment system. We urge the agency to amend its policy decision and adhere to the 80% threshold as appropriate criteria for exclusion of ASC payment.

HRS and ACC do not advocate performance of certain electrophysiology services in an ASC. On November 6, 2006, HRS submitted comments in objection to CMS' proposal (CMS 1506-P) to expand access to certain electrophysiology procedures to the list of services payable in an ASC. HRS remains strongly committed to the safety of patients receiving electrophysiology

procedures, and we reiterate our belief that performance of certain procedures in an ASC facility could pose a significant risk to patient safety. As stated in our previous comments, insertion, repositioning, and extraction of electrodes are complex procedures that have a significant risk of complications. It is appropriate to observe patients overnight when they undergo procedures that have a significant risk of complications. The proposed regulation undermines patient safety. It is contradictory to good clinical judgment and the accepted standards of care. Moreover, we do not believe that the appropriate personnel and equipment are available in the ASC setting to respond to complications that may occur during or after these procedures.

In particular, extraction of electrodes and pulse generators are high-risk procedures that require close and continual observation during the post-operative period. We are extremely concerned that the appropriate level of observation care is not available in ASCs. Additionally, removal of a single lead system electrode is a complex procedure that if improperly performed, could result in the need for emergency cardiovascular surgery. During a lead extraction, there is the risk that a vital part of the heart can be torn with resultant rapid hemorrhage. When this occurs, a cardiovascular surgeon must perform either a full or limited sternotomy, which could not be performed safely in an ASC. An additional potential complication of a lead removal is that the lead can degenerate and require a complete device extraction using a powered sheath. As with a sternotomy, a complete device extraction could not be performed safely in the ASC setting. All of these instances would require the resources available in a hospital, and should not be performed in an ASC.

This concern goes far beyond transvenous lead extraction to the pacemaker, defibrillator and cardiac resynchronization implantation procedures. All of these procedures involve major blood vessels, which is also a criterion for not allowing a procedure to be performed in an ASC. Transvenous electrode procedures involve the placement of electrical leads directly into the heart, which is obviously a major blood vessel. Transvenous leads are inserted through either the subclavian or jugular veins and advanced through the superior vena cava into the chambers of the heart. Left ventricle leads are also passed through the coronary sinus into the coronary veins of the left ventricle. Any procedure that involves insertion, repositioning, replacement or removal of electrical leads directly into the heart involves risk of complications that would require capabilities that are not present in the ASC setting. Furthermore, some state regulations prohibit the performance of certain therapeutic electrophysiology procedures in an ASC facility.

HRS guidelines on performance of lead extractions state the ability to diagnose and treat interthoracic bleeding require the ability to do a sternotomy, have a cardiothoracic surgeon on the premises, and to place the patient on cardiopulmonary bypass, of which none are appropriate in an ASC. These vascular complications are possible with device implantation as

well, and the monitoring that occurs in many of these patients relates to the need to respond to these emergency situations.

HRS and ACC believe that CMS can, and should, make every possible effort to ensure that patients receiving electrophysiology operative procedures are performed in an environment that ensures their safety and reduces risk. We invite CMS to work with the cardiovascular community to determine the appropriateness of the services recently approved and whether they should remain ASC eligible. Please contact Lisa Miller-Jones at (202) 464-3433 or LMiller-Jones@HRSONline.org with any questions regarding our comments.

Sincerely,



Bruce D. Lindsay, MD, FHRS
President, Heart Rhythm Society



James T. Dove, MD, FACC
President, American College of Cardiology