December 21, 2012

Marilyn B. Tavenner, RN
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1590-FC
P.O. Box 8013
Baltimore, MD 21244-8013
Submitted via: http://www.regulations.gov

Re: CMS-1590-FC; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B for CY 2013

Dear Acting Administrator Tavenner:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide comments on the Calendar Year (CY) 2013 Medicare Physician Fee Schedule (MPFS) final rule. HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Founded in 1979, HRS represents specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and their support personnel. Electrophysiology is a distinct specialty of cardiology, and electrophysiologists are board certified in clinical cardiac electrophysiology through the American Board of Internal Medicine, as well as in cardiology. HRS members perform electrophysiology studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization devices in patients who are indicated for these life-saving devices.

The discipline of electrophysiology has undergone significant change in recent years, crossing clinical frontiers in the treatment of cardiology’s most challenging diseases such as sudden cardiac death, atrial fibrillation, and heart failure. As these advancements occur, HRS remains committed to improving the quality, safety, and efficiency of patient care.

Below, we offer comments on specific aspects of the 2013 MPFS final rule. Overall, we support efforts to balance equitable reimbursements with incentives to deliver the highest quality care.

**REVIEWING THE IMPLANTABLE LOOP RECORDER CODES (CPT 33282 AND 33284)**

We disagree with CMS’s plan to have the AMA/Specialty Society Relative Value Scale Update Committee (RUC) review CPT codes 33282 (Implantation of patient-activated cardiac event recorder) and 33284 (explantation of patient-activated cardiac event recorder). In the proposed rule, CMS stated that the codes are not mis-valued. We agree. In the 2013 MFFS final rule, the Agency inaccurately stated that the codes should be reviewed because the site-of-service has changed. There has not been a change in the site-of-service nor are there clinical studies to demonstrate that such a change would be safe and effective for the patients who typically receive these services. There exists a single study of these services conducted in the non-facility setting. That study included fewer than 15 physicians, treating 66 patients. Of those 66 patients, 14 left the study for a variety of reasons.
While HRS is supportive of emerging technologies and new practice settings that improve access to care, there are not sufficient data supporting the need to establish non-facility practice expense relative units (PERVUs). Medicare utilization data for 2010 indicate that the implant service (CPT 33282) was provided in a non-facility setting 0.75% of the time, or 39 times that year. The explant service (CPT 33284) occurred in the office setting 1.88% of the time, or 52 times.

Our physician members have not indicated a desire or demand to provide the service in the office setting. We queried our members about their interest to provide these services in the office setting. We conducted the initial query after we received form letters from nine physicians who were providing the services as part of a manufacturer’s study. We pursued additional input from our members after the release of the proposed rule. The overwhelming response was that electrophysiologists would not be comfortable providing the service outside of a facility due to concerns about safety, sterility and risk of complications.

In meetings with HRS staff, the manufacturer that identified the codes as being potentially mis-valued indicated that the patients who would be eligible for this service in the office setting are NOT the typical patient described in the existing codes. The manufacturer noted that the patients are less complex and have fewer co-morbidities than those captured in the current typical patient vignette. Also, the type of anesthesia required for an office-based implantable loop recorder procedure differs from that delivered to a typical patient.

We recommend that CMS not consider these codes for non-facility PERVUs and should rescind its request for the RUC review these codes.

At this time, we cannot participate in an effort that could be perceived as an endorsement of a shift in the site-of-service, when there is limited data and lack of support among the physicians who provide these services. As we stated in our public comment letter on the proposed rule, until more clinical data is available, we cannot support that these services should be provided in the office setting. We advise that CMS recommend that the requestor attain a Category III CPT code to match the actual services and typical patient or delay this effort until additional clinical research is available to support the clinical validity of providing these services in the office. Once more data is gathered, new Category I codes may be warranted.

**Multiple Procedure Payment Reduction (MPPR)**

We disagree with the CMS strategy to apply the Multiple Procedure Payment Reduction (MPPR) to cardiology diagnostic testing. The CMS proposal violates the RUC process and will create payment anomalies across specialties. This approach discounts the efforts that have been made by the RUC, its Practice Expense Review Committee (PERC) and its Relativity Assessment Workgroup (RAW). The RUC’s PERC and the RAW have dedicated its efforts and numerous specialty societies' resources to identifying potential costs duplications. Reducing the technical component practice expense RVUs for selected services will create payment anomalies across codes making it challenging to apply the RUC’s efforts across codes. CMS's plan will apply an unfair reduction in practice expense payments to a select group of specialties when other diagnostic services provided by specialties are not subject to the payment reduction. In addition, the utilization criteria applied to selecting each service is not a sound methodology.

CMS’s criteria for selecting codes billed together on the same day for the same patient does not rely on similar thresholds that the Agency used in prior payment reduction or bundling policies. For example, CMS has accepted the RUC’s previous criteria of bundling codes that are billed together at least 75% of the time. Currently, the Agency is selecting the top cardiology and ophthalmology
diagnostic code-pairs that in many cases are reported together fewer than 25% of the time. Proposed code-pair reduction 93284 (Programming device evaluation; multiple lead implantable cardioverter-defibrillator system) and 93290 (Interrogation device evaluation (in person) with physician analysis, review and report; implantable cardiovascular monitor system) are billed together fewer than 12% of the time.

Understanding CMS’s effort to reallocate costs toward primary care in a budget-neutral environment, HRS recommends that CMS develop specific criteria, including minimum billing thresholds, and apply the policy to all affected code-pairs across all specialties. Focusing on selected cardiology and ophthalmology services and providing a list of services that are incorrect (e.g., including add-on codes) illustrates that CMS is not prepared to implement this payment change.

We continue to recommend that CMS dedicate future years to work with the RUC and relevant specialty societies to identify existing practice expense duplications and establish criteria to remove duplications across all specialties.

**CMS’s Decision on RUC Work Value Recommendations for New Ablation Codes**

HRS disagrees with CMS’s decision to assign a reduced work value to CPT Codes 93655 (Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure) and 93657 (Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure). According to CMS, CPT codes 93653, 93654, and 93656 are all valued at 5.00 RVUs per 1 hour of intraservice time. In the final rule, CMS asserted that this is the appropriate increment for CPT codes 93655 and 93657 as well, which include 90 minutes of intra-service time and subsequently assigned a work RVU of 7.50 within this family of CPT codes.

The decision to assign the reduced work value to these codes is inconsistent with the RUC’s recommended work RVUs of 9.00 for CPT code 93655 and 10.00 RVUs for CPT code 93657. These services were valued during a deliberate facilitation process. In that meeting, and during our presentation to the full RUC, we clarified that patients receiving ablations for additional foci involve more intense work. Our RUC survey summaries were based on data compiled from over 180 electrophysiologists. Those data captured the difference in intensity between the base codes and the add-on services. Based on the available clinical involvement, on what basis has CMS made the assumption that these services are equally as intense as the base codes in the family? Because of the questions surrounding the process that CMS employed to lower the intensity of these services, we are requesting that the codes be referred to a refinement panel.

The patients, who require these services have had more extensive, refractory disease, requiring additional techniques which are time-intensive, associated with greater risk, and emotional intensity; they also are associated with patients who have had previous attempts at ablation who proved to have recurrent and refractory arrhythmias. A second arrhythmia (93655) is caused by an entirely different physiological mechanism that requires 3-D mapping, complex pacing and recording maneuvers, and greater skill to successfully ablate than the first arrhythmia. A second arrhythmia (93655) is caused by an entirely different physiological mechanism that requires 3-D mapping, complex pacing and recording maneuvers, and greater skill to successfully ablate than the first arrhythmia. Linear ablation to treat atrial fibrillation (93657) requires creation of a line of point ablation lesions a few millimeters in diameter that extends from one anatomical boundary to another—often several centimeters in length. Absolutely no gaps can be left between the point ablation lesions. This would cause pro-arrhythmia. This is one of the most challenging procedures in cardiac electrophysiology. It is intense, time consuming, and adds considerable risk.
For the ventricular tachycardia ablation patients who have ICDs, there is enhanced survival because of defibrillators and at the same time, they often are receiving multiple defibrillator shocks because of ongoing arrhythmias that necessitate ablation. In the process of aging, patients are developing innumerable co-morbidities that make these procedures (which are difficult and complicated at baseline), even more difficult if not risky. The intensity of the experience clearly is more profound. Post-procedural care is more intense and requires greater attention to scrupulous detail. Cases where more than one focus of atrial fibrillation or ventricular tachycardia is required can be lengthy procedures placing the patient at higher risk due to longer exposure to radiation and anesthesia. In addition, the physical intensity on the physician is greater due to spending more time standing while wearing full-body lead protection.

We hope that these comments are useful and look forward to working with CMS staff on these issues. If you have questions about these public comments or would like additional information about HRS activities, please contact HRS’s Director of Reimbursement and Regulatory Affairs, Kimberley Moore at KMoore@hrsonline.org.

Sincerely,

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Immediate Past-President, Heart Rhythm Society