



September 2, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted via: <http://www.regulations.gov>

Re: Comments on the Medicare Physician Fee Schedule CY 2015 (CMS-1612-P)

Dear Ms. Tavenner,

The Heart Rhythm Society (HRS) appreciates the opportunity to provide comments on the CY2015 Medicare Physician Fee Schedule proposed rule. HRS is an international medical specialty society that strives to improve the quality of care provided to patients with cardiac rhythm disorders by advancing research, education, and optimal health care policies and standards. HRS represents medical, allied health, and science professionals specializing in cardiac rhythm disorders from more than 70 countries.

These public comments specifically address:

- Modifications to the Sunshine rule and its application to continuing medical education
- Performance measurement and public reporting-related issues
- Payment provisions including changes to the CPT/RUC calendar, elimination of global periods and classifying electrophysiology services as surgery for malpractice RVU Calculation

SUNSHINE LAW POLICIES

The goal of HRS is to expand the Continuing Medical Education (CME) program consistent with the highest professional standards by addressing the professional practice gaps of physician learners and by facilitating change in participants' competence. HRS is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. HRS was resurveyed by the ACCME in 2012 and awarded Accreditation with Commendation for 6 years as a provider of CME for physicians.

As previously stated in other public comment letters, our concern centers on specific aspects of the 2014 MPFS proposed rule related to payments or other transfers of value to covered recipients, commonly referred to as the "Sunshine Law." Our comments focus on the proposed CME exception, current restrictions on educational materials, physician registration, and dispute resolution process.

CME Exception

As part of the previous rulemaking process, CMS clarified that speaker compensation at certain CME events is not required to be reported by an applicable manufacturer if all of the following criteria were met: (1) the CME program meets the accreditation or certification requirements

and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association; (2) the applicable manufacturer does not select or suggest the covered recipient speaker nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the accredited or certified continuing education programs; and (3) the applicable manufacturer does not directly pay the covered recipient speaker. However, as part of the proposed rule, we are concerned with the proposal to eliminate the exemption for certain CME activities and instead rely on a standard related to whether the applicable manufacturer "does not know" or is "unaware" of the compensation. This less defined standard does not appropriately afford clarity regarding the value of CME. CME is an effective and necessary tool to aid physicians in the acquisition and retention of knowledge, attitudes, skills, behaviors and clinical outcomes necessary to provide high-quality, patient-centered care. Further, this action reverses a decision that CMS had previously reached after reviewing hundreds of stakeholder comments in a comprehensive rulemaking process. This decision, if finalized, would significantly disrupt the practice of CME and the confidence of doctors, educators and others. We urge CMS to reconsider its proposal to eliminate this exception and to opt instead to appropriately expand the list of certified CME accrediting/issuing agencies beyond the five currently cited in regulation.

Educational Materials

As part of the legislation authorizing the Sunshine Act, Congress outlined twelve specific exclusions from the reporting requirement, including "educational materials that directly benefit patients or are intended for patient use." In an interpretation of the statute, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles, and other services used to educate physicians were not covered by this exclusion even though these clearly have a direct benefit to patients and their medical care.

The importance of up-to-date, peer reviewed scientific medical information as the foundation for good medical care is well documented. Independent, peer reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients. The Agency's decision to not cover these materials under the educational materials exclusion is inconsistent with the statutory language on its face, Congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge. We urge CMS to reconsider its decision not to cover medical textbooks, journal article supplements, and reprints within the existing statutory exclusion for educational materials.

Physician Registration

The Society appreciates the time constraints and daunting logistical concerns that CMS faced while implementing Open Payments. In that regard, we applaud the ongoing flow of information facilitated by officials at CMS, which continues to be of great value to the provider community. However, we are concerned that the lack of adequate notice before the beginning of registration periods has handicapped providers that hope to participate in the program in a meaningful manner.

Given the importance of sufficient participation levels and the role of physicians in ensuring data integrity, the Society is concerned that the failure to provide sufficient notice could be a detriment to the program's performance. Further, members of the provider community have legitimate

worries about the lack of guidance and the complexity of enrollment mechanisms. We respectfully ask that CMS provide additional provider-specific guidance for the registration process and adopt policies that allow for flexibility of enrollment requirements so that physicians struggling to enroll remain able to participate in a meaningful manner.

Perhaps most troubling, many physicians are expressing frustration at an overly complex registration process which, combined with the condensed timeframe, makes the task of reviewing and disputing reports by August 27 effectively impossible for the Agency's estimated 224,000 covered physician recipients. CMS has suggested that it will take 30-45 minutes to complete the 5-step process of registering in the Open Payments system. However, given the complexity of the 11-step registration process, which does not include the pre-registration step of verifying identity in Medicare's Enterprise Identity Management (EIDM) System, we believe that the time will be much greater. Moreover, even after registration, to review and dispute data takes an additional five steps layered on top of the already cumbersome registration process. This process must be streamlined and physicians must be given adequate time to review and dispute their reports. Therefore, we ask that CMS postpone for six months, until March 31, 2015, the publication of the information collected in the Open Payments system, to compensate for this year's six months delay in providing the opportunity for physicians to register, contrary to Agency communications throughout 2013 representing that physicians would be permitted to do so beginning January 1.

Dispute resolution process

We remain concerned about the proposed dispute resolution process in which CMS does not take part in the reconciliation process. In the absence of a well-defined reconciliation process, HRS believes that CMS should safeguard the mission of the Open Payments program by taking steps to limit the publication of false information that can impact patient decision-making. However, CMS in its guidance to health care providers stated that information under dispute without reconciliation will nonetheless be posted online for public viewing with a disclaimer. The Society believes that the disclaimer offered by CMS fails to sufficiently protect the reputation of health care providers and provides actionable, but potentially false, information that could impact a patient's decision to choose a health care provider.

Moreover, HRS has concerns that the Agency guidance gives manufacturers the power to unilaterally dismiss disputes that were initiated by physicians or teaching hospitals. These concerns are the result of language that was buried in the supplementary documents of a May 5th Federal Register Notice, stating that manufacturers "after reviewing the disputed information, if they determine that no change is required to the data, may dismiss the dispute or request that physician or teaching hospital who initiated the dispute to withdraw it." The February 2013 Final Rule does not authorize manufacturers or group purchasing organizations (GPOs) to dismiss disputes without both parties agreeing that the dispute is resolved. If no resolution is reached, the manufacturer's or GPO's reported data will be flagged as disputed in the public database until resolution has been reached between the parties. We request that the Agency provide the clarifying guidance to physicians/teaching hospitals, to manufacturers/GPOs, and to our organizations.

As the collector and publisher of financial information, we respectfully ask that CMS enhance the fairness and accuracy of the Open Payments program by ensuring that health care providers have access to a meaningful mechanism for limiting the distribution of disputed information. Current standards fail to meet these goals by creating a reporting system where the default result of any dispute is publication, whether with or without a disclaimer. Such a process fails to fully consider the significant weight that patients may place on the information published by CMS and

the prejudicial effect that even disputed information can have on health care decision-making.

PERFORMANCE MEASUREMENT AND PUBLIC REPORTING POLICIES

Despite an abundance of cardiovascular clinical performance measures, HRS recognizes that few address heart rhythm care as provided by cardiac electrophysiologist professionals. Cognizant that the development of such measures is imperative to promote appropriate accountability and to prepare the field of electrophysiology for the transition to public reporting and value-based purchasing, HRS proactively undertook the development of heart rhythm-specific measures. In pursuing this goal, HRS kept in mind CMS's goal of moving beyond process measurement, where possible, and toward more outcomes-driven care. Since the commencement of the HRS Performance Measure Initiative in 2009, HRS has developed a portfolio of four fully-specified, physician-level performance measures that focus on areas where no others exist to assess performance of electrophysiologists. The four HRS-developed specialty measures were created with an eye towards eventual adoption and use by CMS and others for public reporting and value-based purchasing; three are outcomes measures and one is an important care coordination process measure.

PQRS 2015

Our greatest success in our performance measure initiative was the successful adoption of a heart rhythm care measures in the PQRS. The inclusion of ***HRS-3—Implantable Cardioverter-Defibrillator (ICD) Complications Rate in PQRS 2014*** which assesses the physician-specific risk-standardized rates of procedural complications following the implantation of an ICD (PQRS # 348) makes it feasible for physicians who implant ICDs to participate in procedure-specific performance measurement. This measure also is under review by the National Quality Forum.

The anticipation of our next success is the proposed inclusion of additional HRS-developed measures in the PQRS in 2015:

- ***HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (PQRS Measure Y26); and***
- ***HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (PQRS Measure Y27).***

The rationale for inclusion of HRS-12 (PQRS Measure Y26) is that cardiac tamponade is one of the most serious complications of atrial fibrillation ablation that can lead to substantial morbidity due to a significant drop in the cardiac output and blood pressure leading to hypo-perfusion of important organs such as the brain, heart and kidneys. In many cases, cardiac tamponade has to be treated surgically, and invariably prolongs hospital stay. If not treated promptly, cardiac tamponade can lead to death. The risk of this dreaded complication has been reported to range from 2 to 6%; however, these rates were observed in tertiary referral centers where the procedure was performed by experienced and skillful operators. Given that the occurrence of cardiac tamponade is largely dependent on the operator's level of experience, higher rates are expected to occur when less experienced operators perform the procedure. These issues prove the need to measure performance in this area.

The clinical rationale for the inclusion of HRS-9 (PQRS Measure Y27) is that the rate of implantable ICD infections has been increasing faster than that of device implantation and is associated with substantial morbidity, mortality, and financial cost. A recent study including over 200,000 ICD implant patients found 2 percent of patients undergoing ICD implantation experienced a device-related infection. This evidence demonstrates the need to measure

performance in this area.

ADDITIONAL MEASURE FOR CONSIDERATION

In addition to these two measures proposed for inclusion in the PQRS 2015, we recommend that CMS also consider the below Heart Rhythm Society-developed measure for inclusion in the PQRS. This measure was submitted to CMS during its call for measures for consideration for future rulemaking years in summer 2013. This important care coordination measure will be considered under the second phase of the NQF's *Cardiovascular Measures Project*.

- ***HRS-4—In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)*** assesses the proportion of adult patients with a new CIED implanted during the reporting period who had an in-person evaluation within 2 to 12 weeks following the procedure—either with the electrophysiologist or through coordination with another physician.

The clinical rationale for this measure is that this patient-centered measure addresses follow-up of patients who have undergone implantation of a CIED. A well-established and efficient follow-up program for patients who have undergone implantation of a CIED is important to improve intermediate and longer term outcomes and for purposes of better care coordination. Based on this evidence, the expert clinical guidance recommends that patients with devices have an in-person follow-up appointment 2-12 weeks following implantation and have a yearly in-person evaluation from the time of implantation. This measure also targets an important gap in care. In one study, Medicare beneficiaries eligible for an in-person CIED follow-up after implantation, less than half of the patients had an initial in-person visit within 2 to 12 weeks. The evidence demonstrates the need to measure performance in this area.

Feedback on Measure Submission and Review Process

HRS is an active participant in CMS's measure development and submission process. As a performance measure developer and steward, we offer feedback that may lend itself to a less burdensome process:

- **Submission Form:** The standardized measure submission form lacks sufficient descriptors; how to characterize aspects of a measure is not clear. For example, it was not apparent what CMS considers an "electronic transfer" and how this function differs from claim-based or EHR-based measures. To ensure that the process is more efficient for both CMS and the measure stewards, we request that CMS provides more detailed definitions and explanations of the data elements available on the measure submission form. Ideally, CMS would provide information to measure developers within the sub-regulatory process to ensure that developers understand the parameters and expectations of PQRS measures in advance of measures development.
- **Modifications to Measure Specifications:** With careful and deliberate development and testing of evidence based performance measures, it weakens the process for CMS to make changes to the measure specifications during the time period between proposed inclusion in the PQRS and implementation. For example, changes to the reporting period and minimum procedure volume can deviate from the evidence gathered in the development of the measures. Modified specifications subsequent to the testing process for validity and reliability threat to jeopardize the value of the measure testing. We recommend that CMS provide measure developers with direction about expectations regarding reporting periods, volume of procedure thresholds, and other critical elements of a measure to avoid compromising the integrity of the carefully designed and tested

performance measures. This would enhance the efficiency of this process and reduce unnecessary time and wasting of labor-intensive resources.

We recognize the necessity for CMS to standardize specific data elements such as the reporting period and volume but these efforts should not compromise the integrity of the measures. These issues are particularly challenging for subspecialty societies who have limited resources and develop small measure portfolios. The process should support the efforts to bring highly specialized performance measures to the public and not create unnecessary burden on the developers. We welcome the opportunity to provide additional detail on our experience as measure stewards. We hope our input leads to improvements in the process and enhances access to valid and reliable measures.

PAYMENT POLICIES

Change to CPT/RUC Calendar

We support the effort to provide more transparency by publishing proposed work relative values during the Notice of Proposed Rulemaking. Revising the calendar will allow specialty societies and other interested parties the opportunity to comment on CMS's and/or the RVS Update Committee's (RUC) rationale for valuing services in a more public forum. However, due the complexity of these changes, HRS recommends that CMS delay the proposed calendar change until 2017 plus utilize the meeting cycle plan outlined in the August 13, 2014 multi-specialty sign-on letter about this topic. Since the CPT Editorial Panel and the RUC are reviewing code changes that are within the current 2016 CPT publication cycle, using January 1, 2016 as the effective date for this new calendar would disrupt that cycle. This would adversely impact code changes that already are scheduled to be reviewed by the RUC in September 2014 for publication in *CPT 2016*. Waiting until 2017 will afford time for the 2016 code change calendar to be completed.

HRS also recommends that the Refinement Panel remain in place. The Panel offers an appeals process that is fair to specialties, CMS and other payers. Eliminating the Refinement Panel would be a step backward in transparency even if the code valuations will be open for public comment.

Elimination of 10 and 90-day Global Periods

While HRS understands CMS's reasoning for eliminating 10 and 90-day global periods, there are a number of practice expenses (PE) inputs relevant to post-service care in the global period that the Agency did not address. This proposal should be delayed and CMS should work with the RUC to consider how valuations will be handled.

Practice expense and malpractice RVUs are imperative to appropriately valuing the resources and risks associated with post-op procedural care. In cases such as pacemaker implantation/replacement, follow-up care requires unique direct practice expense inputs (clinical staff type, supplies and equipment) that are not included in the relative values for evaluation and management (E/M) visits. An electrophysiologist who bills an E/M code for a post-procedural visit would not be reimbursed based on the actual resources required to provide that follow-up care. The current methodology to calculate indirect practice expenses relies on the role of direct PE costs. Failing to include the actual direct PE inputs for post-procedural care will result in skewing the actual resources downward, leading to decreased payments for post-service visits. Along with that absence of actual inputs, the malpractice RVUs may be under-calculated, leading to an additional reduction in reimbursement based on actual resources.

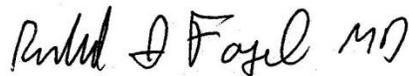
Again, while we understand that the Agency regards eliminating the 10 and 90-day global periods as a mechanism to provide for more straight-forward calculations as payment schemes continue to evolve, this is a concept that requires significant considerations before it can effectively utilized for future payments. The RBRVS relies on calculating actual inputs. CMS's proposal would violate the resource-based approach. We strongly recommend that CMS work with the physician community and the RUC to review the challenges associated with this proposal and to consider potential methods for capturing the actual costs of providing post-procedural care.

Classifying Electrophysiology Services as Surgery for Malpractice RVU Calculation

We appreciate CMS's proposal to classify most electrophysiology, cardiac catheterization and angioplasty services as surgical services for the purpose of setting malpractice premium rates and risk factors. In addition to the codes that CMS identified, we recommend that CPT 92961 (Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure)) be included. This service, which is performed in the Medicare population, only 1,200 times per year, involves significant risk to the patient. Similar to many electrophysiology services, cardioversion requires shocking the heart, forcing it to seize then "re-start".

Thank you for the opportunity to comment on this proposed rule. If you have questions regarding our comments, please contact Laura Blum, Vice President, Health Policy at lblum@hrsonline.org.

Sincerely,

A handwritten signature in black ink that reads "Richard I. Fogel MD". The signature is written in a cursive, slightly slanted style.

Richard I. Fogel, MD, FHRS
President, Heart Rhythm Society