September 11, 2017

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

SUBMITTED ONLINE

Re. CMS-1676-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Dear Administrator Verma,

The Heart Rhythm Society (HRS) appreciates the opportunity to provide CMS with comments on its 2018 Medicare Physician Fee Schedule proposed 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 more than 6,100 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's 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.

Below, we discuss specific sections of the rule that are most pertinent to our members:

Comment Solicitation on Remote Patient Monitoring

CMS seeks comment on whether to make separate payment for CPT codes that describe remote patient monitoring for services that "involved the interpretation of medical information without a direct interaction between the practitioner and the beneficiary" and are therefore paid the same as in-person services without additional requirements of originating sites and the use of the telemedicine place of service (POS) code.

Medicare has a long history of coverage for cardiac remote monitoring. **HRS recommends that CMS consider the coverage experience with respect to cardiovascular implantable electronic devices (CIEDs), as it contemplates expanded access to remote patient monitoring services**. The *HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Implantable Electronic Devices*[1] addresses advancements in technology that allow devices to monitor their own function, record arrhythmias and other physiological parameters. This information can be communicated to beneficiaries' clinicians without the active engagement of the beneficiary.

It is critical that CMS discuss coverage in the context of remote monitoring and remote interrogation. Remote monitoring refers to the automated transmission of data based on pre-specified alerts related to device functionality and clinical events. This provides the ability for rapid detection of abnormal device

[1] Heart Rhythm. 2015 Jul;12(7):e69-100. doi: 10.1016/j.hrthm.2015.05.008. Epub 2015 May 14.

function and/or arrhythmia events. Remote interrogation refers to routine, scheduled, remote device interrogations structured to mirror in-office checkups. Almost all information obtained during an in-office device checkup can now be obtained remotely. In addition, the combination of remote interrogation and wireless remote monitoring allows for nearly continuous monitoring, providing daily self-testing and event notification for out-of-bound parameters, which are not possible for wanded telemetry systems.

In addition to the well-documented clinical benefits, **expanded access to remote monitoring and remote interrogation services through Medicare coverage can increase beneficiary satisfaction.** As noted in the recent HRS consensus statement, several studies have found a high rate of patient satisfaction with patients' perceived relationships with their health care providers, ease of use, psychological impact, and the ability to maintain follow-up compliance[2,3,4,5] and also decreases costs such as travel, time off from work, and the interruption of daily activities for beneficiaries.[6]

The physicians who prescribe remote monitoring have the overarching responsibility for patient monitoring. HRS has noted that remote monitoring programs can vary among medical centers, hospitals, and private practice groups. In certain situations, physicians will have the responsibility for reviewing, interpreting, documenting, and billing for the entire remote report, while others might review data that have first been screened by an allied professional. Mid-level providers (e.g. nurse practitioners or physician assistants) also play an important role. While their role can vary greatly within a remote monitoring program, they typically provide oversight of the allied health professionals in the CIED clinic or might also be called upon to assist with remote alerts and/or patients who have undergone device therapy. The providers typically interact with the patient, obtain a relevant history, review the transmissions, and make recommendations for management. This might require consultation with the patient's attending or collaborating physician. **Physician interpretation and documentation remain the final step**.

HRS supports CMS's request for comment on expanding patient access to remote monitoring services. We believe that future technological advancements will broaden the scope of remote monitoring and remote interrogations services available to patients that can improve patient clinical outcomes and satisfaction and quality of life while providing tools to more efficiently provide care to patients.

Methodology for the Proposed Revision of Resource Based Malpractice RVUs

HRS has significant concerns about the Agency's approach to determining malpractice risk factors for cardiology services. CMS noted that not enough data was available to meet the 35-state threshold for cardiology surgical and non-surgical malpractice data. Data from only 12 states were gathered, thus CMS chose to set a single blended risk factor. We recommend that CMS go back to all available data sources and

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[2] Crossley G, Boyle A, Vitense H, Chang Y, Mead RH. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. J Am Coll Cardiol 2011;57:1181–1189.

[3] Petersen HH, Larsen MC, Nielsen OW, Kensing F, Svendsen JH. Patient satisfaction and suggestions for improvement of remote ICD monitoring. J Interv Card Electrophysiol 2012;34:317–324.

[4] Zanaboni P, Landolina M, Marzegalli M, Lunati M, Perego GB, Guenzati G, Curnis A, Valsecchi S, Borghetti F, Borghi G, Masella C. Cost-utility analysis of the EVOLVO study on remote monitoring for heart failure patients with implantable defibrillators: randomized controlled trial. J Med Internet 2013;15: e106.

[5] Burri H, Sticherling C, Wright D, Makino K, Smala A, Tilden D. Costconsequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK. Europace 2013;15: 1601–1608.

[6] Ricci RP, Vicentini A, D'Onofrio A, et al. Impact of in-clinic follow-up visits in patients with implantable cardioverter defibrillators: demographic and socioeconomic analysis of the TARIFF study population. J Interv Card Electrophysiol 2013;38:101–106.

consider the risk factors for all Medicare-recognized cardiology specialties including interventional cardiology and clinical electrophysiology. Setting the malpractice factor at blended rate of 1.90 significantly discounts the risk associated with a number of electrophysiology services. Most electrophysiology services and procedures are included on CMS's list of Non-Surgical Invasive Cardiology Services. As an example, lowering the malpractice risk factor from 6.87 to 1.9 will result in an overall payment decrease of between 9.2 to 9.9 percent for ablation services to treat tachycardia and atrial fibrillation (CPT codes 93650 through 93657). Pacemaker and defibrillator implantation procedures will see a median cut of 7.65 percent in 2018.

It is not reasonable for CMS to impose significant cuts on electrophysiology and other cardiology services because of a lack of available data when in recent years; CMS has been able to gather that information. **For 2018, CMS should maintain the existing malpractice risk adjustments for surgical and non-surgical cardiology services while gathering the necessary data.** Setting an artificial risk factor goes against the fee schedule's process of setting relativity across services. It is hard to comprehend that implanting a pacemaker, or performing an ablation to treat atrial fibrillation warrants a malpractice risk factor of 1.9 when non-procedural specialties such as licensed clinical social worker has a risk factor of 1.00 and psychiatry's factor is 1.27.

RUC Recommended Work Relative Value Units for Cardiac Electrophysiology Device Monitoring Services (CPT codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, 93292, 93293, 93294, 93295, 93296, 93297, 93298, and 93299)

We are pleased that CMS chose to accept the RUC's recommended work values for the cardiac device monitoring and remote monitoring services (CPT codes 93279 through 93298). While we appreciate the diligence that CMS applied to assess the validity of the RUC's recommendations, we question the basis for their crosswalks to the potential alternative work values. Implementing the RUC's recommended values will maintain the appropriate relativities. As CMS knows, the approach to survey the code set was reviewed by the RUC's Research Subcommittee. The remote monitoring portion of the code-set was surveyed twice, specifically to resolve questions from the RUC. CMS staff heard those discussions and the rationale for our recommendations during the first and second presentations to the Committee. **We recommend that CMS apply all of the RUC-recommended values for the code set in 2018.**

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

CMS continues the implementation of the Medicare AUC Program, as required by statute by the Protecting Access to Medicare Act of 2014 (PAMA). The Medicare AUC Program requires physicians who order advance diagnostic imaging services consult with AUC via a clinical decision support mechanism (CDSM).

CMS proposed to use the first year of the program as an "educational and operations testing year." In 2019, ordering professionals would consult AUC and furnishing professionals would report AUC consultation information on the claim, but CMS would continue to pay claims whether or not they correctly include such information. **HRS believes that this program should be delayed beyond the proposed start date of January 1, 2019. In the interim, HRS supports a true "testing" period that allows for voluntary reporting of these consultations, where payments for claims would not be affected regardless of whether the clinician reported on these data**.

In addition, HRS is concerned about the complexity of these reporting requirements and the burden they would impose on clinicians, facilities, and CMS's own claims processing system. Such a complex program should not be implemented at a time when CMS is carrying out an overhaul of its physician quality reporting enterprise. **HRS urges CMS to take the time to allow clinicians to get used to the Quality Payment Program (QPP) and to work with relevant stakeholders to evaluate how appropriate use of**

imaging can instead be incentivized through the existing structure of the QPP.

Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Individual Eligible Professionals and Group Practices for the 2018 PQRS Payment Adjustment

CMS proposes multiple changes to the 2018 PQRS payment adjustment to ensure fewer clinicians are penalized and that the requirements better align with the Merit-Based Incentive Payment System (MIPS). Among others, the revisions include lowering the number of measures that had to be reported in 2016 to avoid a penalty in 2018 from 9 to 6 and not requiring reporting of measures across 3 domains. CMS also proposes to remove the requirements to report a cross-cutting measure if reporting via claims or qualified registry and the requirement to report an outcome or "high priority" measure if reporting via QCDR. **HRS supports these accommodations, which will result in fewer individual eligible professionals being subject to the 2018 PQRS payment adjustment while imposing no additional burden on them.**

Physician Compare Downloadable Database - Addition of Value Modifier (VM) Data

In thus proposed rule, CMS proposes to not move forward with publicly reporting VM data in 2017 as these data would only be available to the public for one year prior to the end of the program and would not necessarily accurately reflect an EP or group's performance due to proposed changes. **HRS supports this proposal as publicly reporting these data could confuse both clinicians and the public.**

Clinical Quality Measurement for Eligible Professionals Participating in the EHR Incentive Program for 2016

To align with other proposals related to the PQRS, CMS also proposes to change the reporting criteria from 9 clinical quality measures (CQMs) covering at least 3 NQS domains to 6 CQMs with no domain requirement for EPs and groups who, in 2016, chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program. Participants who satisfy the proposed reporting criteria may qualify for the 2016 incentive and may avoid the downward payment adjustment in 2017 and/or 2018, depending on their applicable EHR reporting period for the payment adjustment year. **HRS supports this proposal since it recognizes the complexity of these requirements and the lack of alignment with MIPS, and does not require any additional data collection on the part of clinicians.**

Value-Based Payment Modifier and Physician Feedback Program

CMS proposes modifications to the VM policies for the CY 2018 payment adjustment period to better align with MIPS and ease the transition to this new program. In summary, CMS would reduce the penalty to those who fail PQRS and are thus subject to automatic penalties under the VM. For those who satisfy PQRS and are then evaluated under the VM on quality and cost performance, CMS would hold these eligible professionals harmless from downward performance-based payment adjustments. Since the VM is budget neutral, these proposals also require CMS to reduce the maximum upward payment adjustments that can be earned based on performance under the VM. **HRS supports these policies as they aim to provide a smoother transition to MIPS and minimize penalties across all groups and solo practitioners.**

Patient Relationships Categories and Codes

As part of a multi-pronged effort to improve methodologies for measuring the cost of physician care, Section 101(f) of the Medicare Access and CHIP Reauthorization Act (MACRA) requires CMS to develop classification codes to identify patient relationship categories that define and distinguish the relationship and responsibility of a clinician with a patient at the time of furnishing an item or service.

In this rule, CMS proposes that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable HCPCS modifiers (which

reflect each of the categories), as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). To allow clinicians time to gain familiarity with using these modifiers, CMS proposes that, at least for an initial period, clinicians may voluntarily report these codes on claims. In other words, the selection of the modifiers would not be a condition of payment and claims would be paid regardless of whether and how the modifiers are included. CMS will work with clinicians to educate them about the proper use of the modifiers.

As we expressed in previous comment letters, HRS believes that it is important that clinicians understand and trust that cost measures accurately reflect their performance and their unique role in treating the patient. **As such, HRS supports CMS's efforts to develop patient relationship categories and codes. However, HRS also believes that much work remains both in terms of developing and refining episode-based cost measures to ensure they are clinically accurate and to tie each episode to an appropriate level of "value" for purposes of accountability.** For example, CMS still grapples with how to value specialties like ours that rely heavily on devices and procedures that might be expensive over the short term, but are cost effective over the long term. In addition, CMS still needs to refine risk adjustment methodologies to ensure that resource use measures accurately account for the multiple factors that contribute to the overall cost of caring for a patient.

Since the episode-based cost measures to which the patient relationship categories will be tied have not yet been finalized, it is challenging to know whether these are the most appropriate categories. In order to truly determine whether the categories accurately capture all dimensions of care, we would need to evaluate them in the context of a specific episode. In the case of atrial fibrillation, for example, an electrophysiologist hopes to get a referral and, if appropriate, perform a successful procedure. This course of action may only take 5-6 months of close follow up and then the patient continues it care with his/her primary care physician or cardiologist. However, if the patient needs a second procedure, the episode may extend out 12 or more months and if the patient has a very late recurrence, he/she might come back in 2-3 years before they become another new patient again (according to current Medicare payment rules). Without having a clear definition of the beginning and the end of this episode, it is difficult to characterize the patient-physician relationship with an appropriate label.

There is also the issue of long-term follow up. If, according to the episode definition, an electrophysiologist is expected to follow the patient for 12 or more months, it is unclear whether an electrophysiologist's care would be considered "focused" or "broad." And if focused, would this scenario be considered "episodic focused" or "continuous focused" if the care extended a little longer than expected? Even when episode definitions are finalized by CMS, a physician cannot predict the future and would not necessarily know what code to use to define his/her relationship with the patient at the start of care. While an electrophysiologist hopes to only have to see a patient for 5-6 months, the reality is that it does not always work out that way.

In addition to our concerns about commenting on these categories in the abstract, it is unclear how often physicians will have the opportunity to change these designations as their relationship with the patient evolves or ends. For example, there may be patients for which an electrophysiologist performs "episodic care," such as ablation, but then continues to follow for general cardiology and maybe even primary care. What designation would CMS expect the electrophysiologist to report under this type of scenario-would it have to be consistent throughout or could the electrophysiologist re-define the relationship with the patient over time?

HRS also has concerns about the administrative burden of having to report these additional codes,

especially if they necessitate reporting updates over time. And will physicians have to remember which patients are Medicare, Medicaid, Medicare Advantage, or private payer at the time of coding? Another practical question is how many modifiers can be attached to one claim? Although this can be done on the back end when data is submitted, we are concerned that it could trickle down to the clinician at the time of service and interfere with direct patient care. In general, this additional reporting burden comes at a time when the regulatory and reporting burden imposed upon physicians is at an all-time high.

Finally, if CMS permits physicians to self-designate their relationship with the patient over time, it remains unclear how the Agency will treat situations where multiple clinicians claim the same relationship with the patient. When there are overlapping or conflicting designations, who gets the credit and who is at risk? Also, what if a clinician does not claim primary responsibility for the patient?

Due to the uncertainties, HRS supports CMS's proposal to initially make the reporting of these modifiers voluntary and not a condition of payment. HRS requests that CMS keep this voluntarily for at least several years as it continues to develop and introduce new episode-based measures covering a variety of specialties and subspecialties and as clinicians become acquainted with other reporting requirements under MIPS. To incentivize reporting, HRS also recommends that CMS give clinicians who report these codes credit under MIPS. This could be done either under the Improvement Activities category or under the Cost category in the future, particularly in situations where relevant cost measures have yet to be developed.

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HRS appreciates the opportunity to provide the new Administration with feedback, and we look forward to working with the Agency to refine future policies. If you have questions, please contact Kim Moore, Director of Reimbursement and Regulatory Affairs at kmoore@hrsonline.org.

Sincerely,

George F. Van Hare, MD, FHRS, CCDS, CEPS-PC
President, Heart Rhythm Society