Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

SUBMITTED ONLINE

September 10, 2018

Re: **CMS-1693-P** Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019

Dear Administrator Verma:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on its 2019 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. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. HRS represents more than 6,300 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and their support personnel. Electrophysiology is a distinct specialty of cardiology, with eligibility for board certification in clinical cardiac electrophysiology through the American Board of Internal Medicine, as well as in cardiology.

We limit these comments to the valuation of new electrophysiology procedures, proposed changes to the Evaluation and Management office visit codes and certain quality provisions that impact heart rhythm care.

RUC Recommended Values for Electrophysiology Services

We are pleased that CMS accepted the AMA/Specialty Society RVS Update Committee's (RUC) recommended values for new CPT codes 332X5 and 332X6 for the implantation and removal of a subcutaneous cardiac rhythm monitor. We are concerned that CMS did not accept the RUC's recommendations for new codes 33X05 and 33X06. CMS agreed with the recommended practice expense inputs yet not the work values. **We recommend that CMS adopt these RUC recommendations.**

CPT 33X05 Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed.
CMS proposes to crosswalk 33X05 to code 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular) with a work RVU of 7.80 rather than use the RUC survey 25th percentile recommendation of 8.77. CPT 33X05 has a 61-minute shorter total time, with a half-day discharge and no inpatient visits in comparison to 33207 which has a full-day discharge and one inpatient visit. This point was discussed at the RUC. In one place on the survey, respondents indicated that a visit in the hospital was typical but did not do so in another part of the survey. Ultimately, the medical specialty societies adapted recommendations to remove the visit and recommend the lower survey 25th percentile value instead of the median. An additional important point regarding this population is that the typical patient receiving a leadless pacemaker are sicker and more complex than the typical transvenous pacemaker patient. Patients are selected for this therapy because of their comorbidities or contraindications to traditional transvenous systems. Other issues that make this procedure more challenging are: 1) capture thresholds tend to change more than with transvenous devices, 2) a higher risk for complications including embolization, groin complications which are not associated with tranvenous implants, and tamponade, and 3) patients undergoing leadless pacemakers are more likely to have chronic atrial fibrillation and poor venous access. Even though CMS notes that the work involved in implanting a leadless pacemaker is more intense, the work value reduction resulting from the proposed crosswalk diminishes the increment that was identified by a large pool of survey respondents at the 25th percentile.

CPT 33X06 Transcatheter removal of permanent leadless pacemaker, right ventricular
For CPT 33X06, CMS proposes to reduce the survey-based recommendation by 0.79 work RVUs. This is the same increment that existed between the values recommended by the RUC for these two codes. Instead of values at 8.77 and 9.56, respectively, CMS proposes values of 7.80 (from crosswalk) and 8.59. While these procedures will be rare, these patients will still have the elevated risk factors mentioned in discussion of 33X05 and warrant the additional work indicated by survey respondents at the 25th percentile of the survey.

<u>Revisions to Evaluation and Management Office-Visit Codes</u>
CMS is proposing changes to the Evaluation and Management (E/M) office visit codes. We appreciate CMS' interest in putting patients over paperwork. Easing documentation burdens will improve physicians' interactions with patients. **We recommend that the following plans are implemented to ease administrative burden.**

1. Allow physicians the option to document visits based solely on the level of medical decision making or the face-to-face time of the visit as an alternative to the current guidelines.

2. If physicians choose to continue using the current guidelines, limit required documentation of the patient's history to the interval history since the previous visit (for established patients).

3. Eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient.

4. Eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty,

5. Remove the need to justify providing a home visit instead of an office visit.

We have significant concerns about CMS' intention to revise the E/M coding structure, relative values and payment levels and strongly recommend that CMS halt its plans. Instead, we recommend that the Agency work with the CPT Panel and the RUC to address ways to improve coding and guidelines for office visits and other E/M codes.

Projected Impacts

CMS indicated that the overall impact to cardiology would be a 3 percent decrease in total E/M payments. It is not clear if CMS only considered adjustments to physicians designated under physician specialty code 9 (cardiology) or if physicians designated under Cardiac Electrophysiology and Interventional Cardiology were included in that calculation. **Based on an impact analysis conducted by the American Medical Association, and confirmed by HRS, electrophysiologists would incur a 13% decrease in payments for E/M services.** Due to their patients having multiple comorbidities and complex cardiac needs, EPs typically bill level 4 and level 5 services. Even if EPs would be eligible to bill the specialty add-on code, the additional $14 payment still would result in a total payment lower than the current $109 fee for 99214. We have estimated that should the proposed fee change go into effect, electrophysiologists will lose $29 million in Medicare payments per year solely due to collapsing the payment for level 2 through 5 level services.

Add-on Codes

The proposed rule is not clear about who can bill the specialty add-on code GCG0X *Visit complexity inherent to evaluation and management associated with: Allergy/Immunology; Cardiology; Endocrinology; Hematology/Oncology; Interventional Pain Management-Centered Care; Neurology; Obstetrics/Gynecology; Otolaryngology; Rheumatology; Urology.* The proposed descriptor states "cardiology" but does not delineate if that means only physicians under the cardiology specialty designation, all cardiologists including subspecialists, or if the code applies to billing for treating a cardiac diagnosis. Since CPT codes are not specialty specific, we question the legality of the proposed specialty care and primary care (GPC1X *Visit complexity inherent to evaluation and management associated with primary medical care services)*. In addition, high-intensity specialties such as nephrology, psychiatry and ophthalmology are not included in the list of eligible billers/service. We would like to know how the determination was made to select/not select particular specialty care. **We recommend that these codes are not implemented.**

Impact to Relativity

We are very concerned about the proposal's impact to the relativity used to set Medicare physician fees. The proposal arbitrarily changes the work relative values for the levels 2 through 5 codes, violating the relativity of the Resource Based Relative Value Scale (RBRVS). Changing those values impacts virtually every code in the fee schedule and would make the RUC process of valuing services

and procedures nearly impossible. As an example, a portion of the work values associated with any procedure that has a global period is based on the work values associated with each anticipated follow-up visit. The total work value units for a single chamber pacemaker implantation (CPT 33207) include the values equivalent to one level 3 office visit as part of the care during the global period.

In addition, the change to the practice expense methodology for calculating the proposed practice expense relative value units (PERVUs) for the potential E/M codes changed the indirect practice costs across the rest of the relative value scale. This resulted in a 2-4% decrease in the practice expense values for numerous electrophysiology services. Examples of the shift include:

A 2% PERVU decrease for CPT 33206; insertion of a single-chamber pacemaker;
A 3% PERVU decrease for 33207, insertion of a dual-chamber pacemaker;
A 4% PERVU decrease for CPT 93613, Three-dimensional electrophysiologic mapping; and,
A 4% PERVU decrease for CPT 93653 through 93657, all electrophysiology ablation services.

None of these services have had a revision to their practice expense inputs in a manner that would explain these shifts. Changing the methodology for calculating PERVUs for proposed E/M changes results in a shift across the entire fee schedule.

Throughout the proposal, CMS indicates that it seeks public comment on the proposed code descriptors for the add-on codes, the proposed physician time for the collapsed payment for the levels two through five codes, the proposed work values. CMS also says that the existing code descriptors would need to be re-written but does not indicate in what way CMS would expect to see edits. HRS has immense respect for the work of the CPT Editorial Panel and the RUC. We are pleased to participate in the CPT/RUC E/M Workgroup as it strives to revise the code descriptors and guidelines. **We recommend that CMS not implement the proposed new codes, times and values. Rather, the Agency should continue its partnership with the CPT Editorial Panel and the RUC so that all codes in the Medicare fee schedule are written and valued via a uniform process.**

<u>Merit-Based Incentive Payment System (MIPS)</u>

Low Volume Threshold

For 2019, CMS proposes to expand the criteria for the low volume threshold (LVT) so that it would exclude from MIPS clinicians and groups that meet the following criteria:

- Have ≤ $90K in Part B allowed charges for covered professional services; OR
- Provide care to ≤ 200 Medicare beneficiaries; OR
- Provide ≤ 200 covered professional *services* under the Physician Fee Schedule (PFS)

CMS also proposes to allow clinicians to opt-in to the MIPS program if they meet or exceed one or two, but not all, of the low-volume threshold criterion. As expressed last year, HRS is concerned that a threshold this high could make it difficult to benchmark data because fewer practices would be expected to participate in the program. Electrophysiology faces challenges related to not having enough clinicians reporting on HRS-developed electrophysiology measures to establish a performance benchmark. This largely is due to existing MIPS policies that disincentivize reporting more focused, subspecialty measures. A higher LVT could exacerbate this current problem and discourage

subspecialties from investing in the future development of new measures. Nevertheless, we are pleased that CMS is proposing to allow clinicians to opt-in to the program even if they do not exceed the LVT. We believe this is one of multiple policies that could help contribute to the accrual of subspecialty-specific data.

Group Reporting

CMS continues to receive feedback from stakeholders requesting a mechanism that would allow a portion of a group to participate in MIPS as a separate sub-group and report on measures and activities that are more applicable to the sub-group. CMS notes there are several operational challenges with implementing a sub-group option, and because of potential gaming opportunities. While CMS is not proposing a policy in this rule, it will consider facilitating the use of a sub-group identifier in year four through future rulemaking, as necessary.

HRS continues to have concerns that subspecialists in larger multi-specialty groups have limited control over the selection of measures and reporting mechanisms that are best for their practice. For example, despite HRS's investment in multiple electrophysiology-specific measures, which have been available for multiple years, very few electrophysiologists rely on these measures for purposes of reporting to CMS because they are part of larger cardiology or multi-specialty practices operating under the same Tax-ID Number (TIN) that dictate measure selection. These low-use rates are unfortunate and concerning for multiple reasons. They limit CMS' ability to establish a benchmark on which to assess performance, which means that the few electrophysiologists who do report these measures are automatically at a scoring disadvantage. We are also concerned that CMS might decide to remove these measures from the program in future years based on low reporting rates, when in fact, there is great interest among our members to use these measures if there was an incentive and mechanism to do so. **We urge CMS to adopt policies that encourage the tracking of subspecialty data and promote the reporting of measures that include the granularity needed to understand and improve upon heart rhythm care.** CMS should recognize quality improvement efforts at multiple levels and calculate performance in a manner that is congruent with the varied ways that providers practice and are organized.

Performance Category Weights

CMS proposes the following weights for 2019:

- **Quality**: 45% (down from 50%)
- **Cost**: 15% (up from 10%)
- **Promoting Interoperability**: 25% (no change)
- **Improvement Activities**: 15% (no change)

HRS recommends that CMS not raise the weight of the Cost category. The Bipartisan Budget Act of 2018 provided CMS with flexibility to weigh the Cost category at between 10% and 30% of the MIPS composite score for an additional three years. CMS should take advantage of this flexibility and maintain the Cost category weight at 10% since the cost measures used in this program are still flawed, under refinement, or too immature for implementation.

Quality

Performance Period

CMS proposes to maintain the calendar year performance period for the Quality performance category, as well as the 90-day performance period for the Improvement Activities and Advancing Care Information (ACI) categories. HRS remains concerned that the use of different performance periods adds to the complexity of this already complicated program. It also contradicts one of the most important goals of MIPS, which is to streamline reporting requirements across performance categories. **We strongly urge CMS to revert back to the 90-day performance period for Quality and to aim for alignment of policies as often as possible.**

Cost

As noted earlier, HRS opposes CMS' proposal to increase the weight of the Cost category at the expense of the Quality category. There is still much work to be done to identify the most appropriate measures and apply the most appropriate risk adjustment and attribution methodologies. We continue to favor more granular, episode-based cost measures emphasizing measures that are relevant to and that can be specially addressed by each specialty or subspecialty over the existing Total Per Capita and Medicare Spending Per Beneficiary measures. HRS remains disappointed with CMS' decision to retain these two broader measures. As episode-based cost measures become available, they should supplant rather than supplement these two highly flawed cost measures. At the same time, the episode-based measure development work is still in its infancy. While we appreciate the involvement of clinical stakeholders in the development of these measures, the broader community of clinicians not involved in this process did not have enough time to digest and provide feedback on these measures.

HRS also recommends that CMS identifies ways to improve accounting for less evident inputs that contribute to the overall value of care, such as upfront investments (e.g., the cost of medical devices) that might accrue long-term savings as they relate to better outcomes and reduced costs elsewhere in the health system. Similarly, there is an ongoing discordance between what CMS is choosing to measure on the cost side versus what it is measuring on the quality side. Ultimately, appropriateness of care, which accounts for both quality and spending, in a value-based program should be the overall goal rather than measuring raw cost data in isolation.

Promoting Interoperability (PI)

CMS proposes to require clinicians to transition to 2015 Edition Certified Electronic Health Record Technology (CEHRT) in 2019 in order to get credit under this performance category. **We reiterate our request from last year that CMS not require clinicians to transition to the 2015 Edition CEHRT. While there are legitimate reasons to incentivize movement towards 2015 CEHRT, clinicians that are unable to do so at this time should not be penalized.**

CMS also proposes to reduce the number of measures and to simplify the overall scoring methodology of the PI Category. CMS would eliminate the base, performance, and bonus scoring structure and instead use a single performance-based methodology, rather than the previous threshold approach. HRS appreciates this more simplified approach; however, it still relies on an all-or-nothing approach since a clinician must report on every single measure to receive a score in this category.

We recommend that CMS adopt its alternative proposal, which would give clinicians the flexibility to report one measure from each objective rather than requiring reporting on all measures.

Over the long term, we believe that more fundamental reforms are needed for this category. MIPS represents an important opportunity to give clinicians the flexibility to demonstrate meaningful use of EHRs in more innovative ways that account for differences in practice makeup, infrastructure, and experience with health information technology. **Going forward, CMS should take more concrete steps to move beyond what is still largely a one-size-fits-all approach that focuses more on EHR functionality than true improvements in patient care.** To realize the full potential of EHRs, requirements under this category need to be less prescriptive to allow clinicians to creatively incorporate technology into their unique clinical workflows and to respond to their patients' needs.

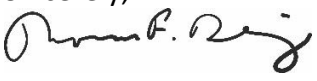
We also observe that across medicine and within our subspecialty, the primary challenge with HIT continues to be a lack of interoperability standards. The Implantable Device Cardiac Observations (IDCO) Profile, developed by HRS, sets an industry standard for all clinical terminology related to these devices and provides a standard protocol for communicating the data across IT systems. We continue to work with clinicians and all manufacturers to expand the capabilities and implementation of the IDCO Profile. CMS must focus on resolving similar basic IT architecture and taxonomy issues necessary for data exchange and on increasing the functional interoperability between HIT vendors and among vendors and registries to ensure this aspect of MIPS are achievable, meaningful, and not another inefficient regulatory burden on clinicians.

MIPS Performance Threshold

In this rule, CMS proposes to increase the MIPS Performance Threshold, or the dividing line between upward and downward payment adjustments, from 15 points to 30 points. CMS also proposes to increase the exceptional performance threshold from 70 points to 80 points for 2019. HRS opposes CMS' proposal to double the MIPS Performance Threshold. **We recommend that CMS more gradually increase this threshold given the ongoing complexity of the program and insufficient historical MIPS data on which to set benchmarks and determine the feasibility of the current performance threshold.**

We appreciate the opportunity to comment on these topics. Should you have any questions, please contact Kimberley Moore, HRS' Director of Reimbursement and Regulatory Affairs at KMoore@hrsonline.org.

Sincerely,



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