



The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: **CMS-1715-P**  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

September 19, 2019

*Submitted electronically*

**Re: File Code CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 14, 2019)**

Dear Administrator Verma:

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on the Medicare Physician Fee Schedule Proposed Rule for calendar year (CY) 2020. 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 6,700 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.

Our comments below focus specifically on proposals related to the Quality Payment Program (QPP). Please also refer to our letter, submitted on September 6, 2019, which offers comments on payment provisions related to the Physician Fee Schedule. Those comments focused on the malpractice Risk Factor for clinical electrophysiology, AMA/Specialty Society Relative Value Scale Update Committee recommendations for CPT codes 93297 and 93298, and applying the increase in work relative value units for evaluation and management services to codes with 10 and 90-day global periods.

### **MVP Framework**

Since the QPP launched in 2017, CMS has taken incremental steps to update both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) participation tracks to acknowledge variation in clinician practices and to further refine program requirements to reduce reporting burden and encourage more meaningful engagement among clinicians. However, CMS has heard from clinicians that the program, specifically MIPS, remains overly complex.

To respond to these concerns, CMS proposes MIPS Value Pathways (MVPs), a conceptual participation framework that would apply to future proposals beginning with the 2021 performance year. The goal is to move away from siloed activities and measures and move towards an aligned set of measure options more relevant to a clinician's scope of practice that is meaningful to patient care. Overall, CMS believes the MVP framework would help to simplify MIPS, create a more cohesive and meaningful participation experience, improve value, reduce clinician burden, and better align with APMs to help ease the transition between the two tracks. CMS also anticipates that these MVPs would result in comparable performance data that helps patients make more informed health care decisions.

**HRS appreciates CMS' effort to transform MIPS into a more streamlined and meaningful program and its ongoing consideration of stakeholder input. However, we have concerns about aspects of the framework, which are listed below, that we hope CMS will consider as it further specifies this proposal:**

- **To truly streamline the program, CMS must take more concrete steps to break down the silos that currently result in four disjointed MIPS performance categories that each have a distinct set of measures, reporting requirements and scoring rules.** Clinical actions captured by measures and activities should translate into credit across multiple performance categories to unify the program and minimize administrative burden.
- **Encourage meaningful participation among specialists.** As CMS implements the MVP framework, it should maintain a diverse inventory of specialty-specific measures and activities and adopt simplified scoring policies that incentivize the use of such measures and activities and the accrual of enough data to calculate performance benchmarks. HRS also supports CMS providing specialists in a multi-specialty group the option to participate in MIPS as a subgroup using the MVP approach. Currently, specialists in larger multi-specialty groups, such as electrophysiologists, have limited control over the selection of measures and reporting mechanisms that are best for their unique patient population. By allowing portions of a group to participate through more focused MVPs, multi-specialty practices could more comprehensively capture the range of services furnished by specialists in a group, which would result in more meaningful data for both clinicians and patients.
- **Develop MVPs under a transparent process that relies on relevant clinical stakeholder input.** MVPs should be developed and implemented gradually through pilot testing that focuses on relatively straightforward conditions and procedures that have existing measures and activities.
- **Adopt non-mandatory participation options.** CMS contemplates assigning clinicians and groups to MVPs in the future. It is essential that clinicians maintain the ability to choose the most appropriate MIPS participation pathway—whether that is through an MVP or traditional MIPS. If an MVP is the preferred pathway, the clinician or group should have the ability to select which MVP is most appropriate based on CMS guidance.
- **Minimize reliance on administrative-based population health measures.** Although we support efforts to minimize reporting burden, we do not believe that administrative-based population health measures are an appropriate solution since 1) they rely on a data source that does not always show a complete picture of care and 2) they do not result in relevant or actionable feedback for specialists. These types of measures are more appropriate for alternative payment model or health plan-level accountability programs.
- **Recognize more innovative and cross-cutting ways of measuring clinicians under the Promoting Interoperability (PI) category.** CMS suggests that, at least initially, the MVPs would rely on the current set of PI objectives and measures. As we have stated in the past, clinicians should have 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. It is critical that CMS 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 patient's needs. Additional details are provided in this letter.
- **Provide enhanced and timelier performance feedback to clinicians.** This feedback should be provided in as close to real-time as possible in a format that can be easily accessed and understood by clinicians. Data should be actionable and capture elements of care over which specialists have direct control.

## **MIPS Policies Proposed for 2020 and Beyond**

### **Frequently Shifting Requirements**

In this rule, CMS proposes again to shift the weights of the MIPS performance categories in 2020.

While HRS appreciates the need to raise the bar on quality and value, these year-to-year shifts in policy are challenging for clinicians. We appreciate and support CMS's effort to fundamentally reform MIPS through the MVP framework, but at the same time, it is important that CMS also maintain a consistent traditional MIPS pathway where program rules and performance thresholds remain the same for at least a few years. This would allow CMS to accurately gauge participation trends, the feasibility of certain policies, and the appropriateness of specific measures and activities.

As we have expressed in the past, HRS also opposes CMS' proposal to increase the weight of the Cost category at the expense of the Quality category due to numerous ongoing issues related to existing cost measures, including the need for additional education and outreach so that clinicians can better understand the current set of cost measures; the potential for double accountability when specialists are measured under both the Medicare Spending Per Beneficiary (MSPB) measure and an episode-based cost measure; and the failure of these measures to account for less evident factors contributing to the overall value of care, such as upfront investments (e.g., the cost of medical devices) that might accrue long-term savings in terms of better outcomes and avoided costs elsewhere in the health system. Furthermore, clinicians have far more direct control over quality measures than they do over the current set of cost measures and the category weights should reflect this reality.

### **Policies That Disincentivize the Use of Specialty Measures**

Beginning with the 2020 performance period, CMS proposes to remove quality measures that do not meet case minimum and reporting volumes for benchmarking for two consecutive years. If CMS were to finalize this policy, it could threaten the availability of the only three MIPS measures that are directly relevant to electrophysiologists, which are:

- #348: Implantable Cardioverter-Defibrillator (ICD) Complications Rate
- #392: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation
- #393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

HRS opposes this proposal. HRS invested heavily in the development of these outcome measures and all three are considered high priority measures by CMS. To encourage more meaningful engagement among subspecialists such as electrophysiologists, it is critical that CMS maintain as broad of an inventory of measures as possible, while simultaneously adopting rules and participation pathways that incentivize the use of more focused measures by specialists. This could include policies that allow for subgroup reporting (as discussed in the MVP section) and/or providing bonus points or a minimum number of points to clinicians who report on measures without benchmarks.

CMS also contemplates removing the current 3-point floor for measures that meet the data completeness threshold, but do not have either a benchmark or at least 30 cases. We also oppose this policy and urge CMS to instead give credit to clinicians who take the time to report data under MIPS and contribute to the building of performance benchmarks. It is important that CMS recognize that low reporting rates are not unusual or an indication of a low value measure for highly specialized procedures or patient populations. Some measures may only be reported by a small number of clinicians and yet that small number represents a significant percentage of those caring for the patients to which the measure applies.

### **Promoting Interoperability**

As we noted earlier, HRS believes that more fundamental reforms are needed for this category. MIPS represents an important opportunity to give clinicians the flexibility to demonstrate meaningful use of health information technologies in more innovative ways that account for differences in practice makeup, infrastructure, and experience with technology. 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 patient's needs. Preferably, clinicians should be able to attest that they are using CEHRT or health information technology (HIT) that interacts with Certified Electronic Health Record Technology (CEHRT), rather than reporting on individual "Promoting Interoperability" measures. If CMS uses specific measures to capture clinician performance in this category the Agency should also offer a larger inventory of measures that focus on innovative ways of capturing, applying and sharing electronic data (e.g., implementation of practice improvements based on patient-generated electronic health data; the use of clinical registries that incorporate EHR data that allow clinicians to better communicate with patients).

For electrophysiologists, the primary, ongoing challenge with HIT is the lack of interoperability. Interoperability is the cornerstone to developing a robust health information technology network that could be used to improve quality and efficiency. In addition, the lack of interoperability standards is a key barrier to improving patient safety in HIT. The HRS looks forward to continuing to work with federal agencies, including CMS and ONC, as well as private industry on solutions to current interoperability challenges and metrics that fairly account for any ongoing limitations to data exchange.

### ISO/IEEE 11073-10103:2014 Nomenclature

Since 2005, HRS has partnered with clinicians and engineers from the four major manufacturers of implantable pacemakers and defibrillators as well as other medical societies under the guidance of Integrating the Healthcare Enterprise (IHE) to develop a common nomenclature that encompasses the key concepts required to manage patients with these devices, regardless of manufacturer. On August 27, 2012, the Institute for Electrical and Electronics Engineering (IEEE) approved the controlled vocabulary for CIEDs. Subsequently, it was approved as an international standard by the International Standards Organization (ISO) and recognized by the U.S. Food and Drug Administration and became known as ISO/IEEE 11073-10103:2014 (Health informatics -- Point-of-care medical device communication -- Part 10103: Nomenclature -- Implantable device, cardiac).

Unfortunately, the device manufacturers have not fully implemented the data standard in commercial products. Therefore, the data for patients with implanted pacemakers and defibrillators remains locked in proprietary formats, available primarily in display formats such as PDF, with data not directly abstracted, primarily suited for scanning into electronic records. HRS and its clinical partners continue to develop the nomenclature and advocate for its implementation by the vendor community. However, vendors have seen no financial or other compelling incentive to implement it.

Work is currently underway by the HRS Interoperability Working Group to revise the existing IEEE 11073-10103 nomenclature to further decrease the ambiguity in the data structure and to enhance its utility by adding additional terms needed made necessary by advancing technology.

### Implantable Device Cardiac Observation (IDCO) profile

In addition to collaborating on the ISO/IEEE 11073, HRS and the cardiac rhythm management (CRM) industry (all vendors represented) are working on the Implantable Device Cardiac Observation (IDCO) profile. This profile specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemaker (PM), implantable defibrillators (ICDs), and cardiac resynchronization therapy device (CRT) interrogations (observations) or messages. The profile was tested, validated and certified by the IHE's rigorous standards development process. It contains over 200 data elements identified by HRS clinicians as necessary and enough to evaluate and monitor the function of all pacemakers, ICDs and CRT devices regardless of vendor.

Work on the IDCO profile was initiated in 2005. The IDCO profile was developed out of recognition that patient safety, quality, and efficiency of care required an interoperability standard to close this gap. The IDCO interoperability profile is now available for implementation and clinical use. Yet, we have been unsuccessful in convincing the CRM industry to implement the full IDCO profile in their market release products. This has limited our ability to seek adoption and implementation by the electronic health record industry and personal health record vendors. It also has limited our ability

to encourage utilization of the interoperability profile for data registries, quality monitoring, and post-market approval FDA surveillance studies.

Collaboration with federal agencies will be necessary in order to realize the full potential of meaningful interoperability of data acquired from PM's, ICDs and CRT devices. HRS encourages CMS to work with the Office of the National Coordinator for Health Information Technology to first resolve basic cornerstones necessary for data exchange and to streamline and standardize data exchange between HIT vendors, registries, and third-party applications to ensure that the PI category is actually achievable, and meaningful.

### **CMS Requests for Information (RFI)**

#### RFI on Engaging in Activities that Promote the Safety of the EHR

HRS remains concerned with the lack of structured mechanisms by which health IT-related patient safety events can be reported to, and subsequently addressed by, the facilities where electrophysiologists deliver patient care. We have previously urged ONC to work with CMS to update the Quality Assessment and Performance Improvement (QAPI) Condition of Participations to require hospitals and other facilities to include their medical staffs, including electrophysiologists, in health IT purchasing decisions and implementation processes, as well as establish a process that would facilitate reporting of patient safety issues associated with EHR use and timely responses to medical staff concerns about patient safety and other HIT issues during and after implementation.

#### RFI on the Integration of Patient- Generated Health Data into EHRs Using CEHRT

Affordable consumer wearable devices, sensors, and other technologies capture patient-generated health data (PGHD), providing new ways to monitor and track a patient's healthcare experience in between in-person visits, which may improve care management and patient outcomes. Although many types of PGHD are used in clinical settings today, the continuous collection and integration of patients' health-data into EHRs to inform clinical care has not been widely implemented. CMS is interested in feedback on how the PI category could incorporate new elements related to PGHD that represent clearly defined uses of health IT, are linked to positive outcomes for patients, and advance the capture, use, and sharing of PGHD. CMS states that the bi-directional availability of data, where both patients and their health care providers have real-time access to the patient's EHR, is critical. According to CMS, this includes patients being able to import their health data into their medical record so that it is available to clinicians.

Physicians are increasingly faced with the task of processing and interpreting large amounts of clinical information that their patients have collected on consumer wearable devices. A critical challenge with this trend is that data are not always standardized and may not easily integrate with the EHR. For example, wireless home monitoring is now the standard of care for patients with implantable pacemakers and defibrillators. However, these devices generate large quantities of data which must be organized, interpreted and stored. Each manufacturer has developed proprietary software and terminology, which prevents the data from being incorporated into the EHR in a format that is usable by clinicians. This compromises patient care and requires clinicians to devote time searching in proprietary vendor databases for important clinical information. It also compromises the ability of patients to access data from their pacemaker or defibrillator.

HRS supports efforts to provide patients with greater access to their healthcare data. However, the value of greater patient access to their data should be balanced with the potential implications of making data immediately accessible to patients prior to a clinician's review. There is a risk of "information overload" for the clinician and the patient. Immediate access to data can also raise concerns about data security, and physician responsibility and liability to manage, decipher, and prioritize the clinical information.

More work is necessary to develop systems for standardized electronic collection, filing, and storage of this information in EHRs in a usable format. Part of this work must include developing pathways by which physicians are notified when

patients upload new data, tools for secure electronic two-way communication between the patient and health care provider and developing appropriate and reasonable expectations regarding timing of data review by health care providers. As patients have greater access to their data, it is critical that regulations, including physician payment policies, evolve to reflect the additional demands.

### **Improvement Activities**

As CMS continues to expand the inventory of acceptable activities, we reiterate our earlier recommendation that it recognize clinicians who have contributed to the development and/or implementation of interoperability standards and profiles. Many of our members have been involved with the development of an Implantable Device Cardiac Observation (IDCO) profile, which specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemakers, ICDs, and cardiac resynchronization therapy device interrogations (observations) or messages. These standards are critical for more robust engagement in quality measurement and meaningful use of health information technology to improve the quality of patient care. This also represents a cross-cutting improvement activity that could reduce reporting burden by allowing a clinician to satisfy multiple performance categories at once under MIPS.

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HRS thanks CMS for the opportunity to comment on these QPP proposals. We look forward to working with you on these and other topics as you develop the final rule for FY2020. For questions, please contact Isabelle LeBlanc, Director, Health Policy at [ILeBlanc@hrsonline.org](mailto:ILeBlanc@hrsonline.org).

Sincerely,



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