The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

September 21, 2020

Dear Administrator Verma:

The Heart Rhythm Society (HRS) offers the following comments on the Proposed Medicare Physician Fee Schedule for calendar year (CY) 2021. 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 7,100 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied professionals. 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 certification in cardiology.

Our comments will focus on payment changes due to revisions to the evaluation and management services, the proposed add-on code for inherent complexity, the application of E/M increases to codes with 10 and 90-day global periods, CMS' response to Relative Value Scale Update Committee *(*RUC) recommended work values for certain electrophysiology services, and proposed updates to the Quality Payment Program.

Evaluation and Management (E/M) Visits

Budget Neutrality Adjustment Impact on CY 2021 Medicare Physician Fee Schedule

While the major proposals regarding office and outpatient evaluation and management (E/M) documentation and valuation were finalized in CY 2020 rulemaking with a January 1, 2021 effective date, the impending implementation date has triggered the administration of statutory budget neutrality requirements. This redistribution inside the Medicare Physician Fee Schedule (MPFS) caused by the office and outpatient Evaluation/Management (E/M) policies finalized last year (along with newly proposed policies for "refinements to values for certain services to reflect revisions to payment for office/outpatient E/M visits") has resulted in a projected decrease to the MPFS conversion factor of -10.6 percent, which would send the MPFS conversion factor plummeting to a level not seen since the early 1990s. While we continue to support the RUC recommendations that serve as the base for the office and outpatient E/M

policies, ***HRS urges CMS and the U.S. Department of Health and Human Services to refine its policies in order to mitigate the negative impact that will result from the drastic reduction in the CY 2021 MPFS conversion factor proposed by CMS.*** While we appreciate the statutory requirements for budget neutrality, we believe that there are several steps that CMS can take under current authority by (1) eliminating or postponing the implementation of E/M "inherent" complexity code, GPC1X; (2) extending commensurate increases in the valuation of the office and outpatient E/Ms to 10- and 90-day globals; and (3) pursuing public health emergency (PHE) authorities that would allow the secretary to waive or mitigate the impact of budget neutrality in order to assist practices in navigating and recovering from the ongoing COVID-19 pandemic. Electrophysiologists are experiencing unique pressures delivering care during this pandemic given that many electrophysiology practices had to stop performing all procedures and as of today have not returned to full clinical capacity. As a specialty that submits claims for office and outpatient E/Ms at a very low frequency (thus not benefiting from the large increases to those services), a -10.6% reduction to the MPFS conversion factor in CY 2021 will only increase the pressures on heart rhythm care at the time we should be providing those practices with *more* support and resources, not less.

E/M "Inherent Complexity" Add On Code

In the proposed rule, CMS briefly discusses the previously finalized add-on code GPC1X. In last year's rulemaking, CMS finalized the following code descriptor for GPC1X:

> GPC1X (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*).

CMS acknowledged stakeholder input regarding the appropriate use of this code and lack of clarity around the documentation requirements for billing it. In seeking additional input on where clarity might be needed, CMS also stated that it envisioned that, for specialty care, the

> *HCPCS add-on code GPC1X could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals.*

HRS does not agree that this code should exist. Within the E/M codes, additional work is recognized by billing a higher-level code, or when appropriate, applying a modifier. Including GPC1X will cause significant confusion among physicians and billing professionals. Revising the outpatient E/M codes was intended to remove confusion. GPC1X will complicate correct coding.

We appreciate CMS' acknowledgement of the work that specialists furnish to manage and direct patient care. However, the care that many specialists, including electrophysiologists, deliver that is

included in CMS' description above occurs outside the context of an office and outpatient E/M service, making the use of GPC1X impossible given that it is an office/outpatient E/M add-on code. We believe this highlights the confusion around this code and what physician work and clinical scenarios this code describes. For these reasons and because of the outsized impact the introduction of this code has on budget neutrality and the CY 2021 MPFS conversion factor, ***HRS urges CMS to cancel HCPCS code GPC1X and await input on recommendations from the AMA CPT Editorial Board and the AMA*** **Specialty Society Relative Value Scale Update Committee *(*RUC).** ***RUC on whether this code has a place in the CPT construct and in the context of all other fee schedule services and to make more accurate, resource-based recommendations on its use and valuation***.

Valuation of Evaluation and Management Services for 10 and 90-Day Global Services

In CY 2020 rulemaking, CMS declined to follow its past precedent by failing to proportionally extend the increases in the values of the office and outpatient E/M to 10-and 90-day globals where those visits are packaged. ***HRS urges CMS to apply the finalized work values for the office and outpatient E/M codes to the post-procedural visits within the global services package as recommended by the*** **RUC.** CMS should carry the new work values for E/M codes to the global services visits to maintain relativity across the fee schedule. CMS directly undermines the entire system of relativity on which the Resource-based relative value scale (RBRVS) is based by not making commensurate increases in values where the value is derivative of the office and outpatient E/M codes. In fact, CMS does this in multiple different contexts in this year's rulemaking in the section, "refinements to values for certain services to reflect revisions to payment for office/outpatient evaluation and management (E/M) visits" but fails to do so for 10- and 90-day globals as it has done in the past.

While we share CMS' objective of promoting the accuracy of all code values in the MPFS, if CMS implements this policy as proposed it will make it increasingly difficult to appropriately value services with 10- and 90-day global periods. By citing CMS concern about whether global codes have accurately packaged the correct number of E/M visits in the global period as a reason to not commensurately update the global code values, CMS has erroneously and arbitrarily conflated the issues of value accuracy and relativity. In addition, CPT codes are not specialty specific and statute forbids CMS for paying physicians differently for providing the same service on the basis of specialty type. Failing to apply the updated RVUs for a follow-up visit packed into a global period that is considered a level 3 E/M codes should not be considered to involve less work than a stand-alone level 3 E/M visit. CMS' policy skews the entire fee schedule, inappropriately re-allocating work values based on a non-relative approach. If CMS believes that codes are inappropriately valued, it should work with the RUC to review the specific codes for accuracy. Instead, CMS is attempting to implement a flawed policy that would undermine core tenets of the RBRVS. ***CMS should reconsider its policy and finalize the RUC recommendations related to updating the values of global codes which included packaged office and outpatient E/Ms.***

CMS Response to RUC Recommended Work Values for Electrophysiology Services

Pacing Heart Stimulation (CPT Code 93623)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
93623	**Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)**	**0.98**	**2.04**

For the Pacing Heart Stimulation code (93623), CMS has disagreed with the RUC recommended work RVU. CMS has proposed to decrease the work RVU from 2.04 to 0.98 for code 93623. CMS believes that their pick of an alternate work RVU more closely aligns with the valuation of this code than the RUC recommended. However, the RUC recommended work RVU for code 93623 is based on survey data. CMS should use valid survey data in establishing the work RVU for this code. The RUC thoroughly analyzed this code by review of history, survey data and magnitude estimation to other similar services. Details on why CMS should accept the RUC recommendation for this code is outlined below.

For CPT code 93623, the RUC recommended a work RVU of 2.04. CMS disagrees with the RUC recommended work RVU of 2.04 and is proposing a work RVU of 0.98 for code 93623 based on the significant change "from the current 60 minutes to 20 minutes" in intra-service/total time. The Agency does not believe that the RUC recommended work RVU appropriately accounts for the reduction in intra-service time for this service. The RUC completely disagrees with CMS' proposed recommendation of 0.98 work RVUs for code 93623. The current time source for CPT code 93623 is CMS-Other. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS-Other, implying that the time was merely cross walked or selected by a CMS staff person some time ago.** CPT code 93623 had never been surveyed by the RUC; the intra-service time established by the CMS-Other source is what the current work RVU is based on. Therefore, CMS' rationale to further reduce the recommended work RVU based on the reduction of the "current" intra-service time of 60 minutes in comparison to the RUC recommended intra-service time of 20 minutes from robust survey data for code 93623 is unjustified. Additionally, the RUC's recommendation of 2.04 for code 93623 will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

Furthermore, CMS compares code 93623 to reference code 76810 (*Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure*) (work RVU = 0.98, intra-service and total time of 20 minutes). CMS is incorrect in proposing the work RVU of 0.98 when referencing code 76810 because the nature of the services performed, time, intensity and work involved are vastly different. The only commonalities between 93623 and 76810 are that they are both add-on codes and have 20-minute intraservice times. 76810 includes supervision of sonographer and interpretation of an ultrasound of an additional fetus—e.g., a

twin. During 93623, isoproterenol is infused to the heart through a central line port, ideally increasing the patient's heart rate 20% above baseline, during a 60-minute period. Isoproterenol is a potent nonselective beta-adrenergic agonist with very low affinity for alpha-adrenergic receptors. Intravenous infusion of isoproterenol lowers peripheral vascular resistance thereby decreasing diastolic pressure. Cardiac output is increased because of the positive inotropic and chronotropic effects of the drug in the face of diminished peripheral vascular resistance. The cardiac effects of isoproterenol may lead to palpitations, sinus tachycardia, and more serious arrhythmias, which may ultimately require treatment via catheter ablation. A patient requiring isoproterenol experiences significant hemodynamic changes and tachyarrhythmias, while a patient receiving the ultrasound is simply found to have twins, a vastly different state of health; one requiring observation and the other requiring treatment. Pacing stimulation is significantly more intense with acute risk to the patient during an already complex, underlying procedure.

The RUC recommendation for CPT code 93623 was based on the survey 25th percentile work RVU from robust survey results of 46 cardiologists as well as a favorable comparison to the top key reference service (KRS) 93463 *Pharmacologic agent administration (e.g., inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (list separately in addition to code for primary procedure)* (work RVU = 2.00 and intra-service time of 30 minutes). Survey respondents who selected the pharmacologic agent administration code 93463 as the top key reference service found code 93623 to be more intense/complex overall. The RUC agreed that this comparison is reasonable since survey respondents estimated CPT code 93623 to involve a similar amount of work to CPT code 93463. The RUC also referenced MPC code 36227 *Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)* (work RVU = 2.09 and intra-service time of 15 minutes) and agreed that both reference services bracket code 93623 in both physician work and time, strongly supporting the RUC recommended work RVU of 2.04. **The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is CMS-Other, implying that the time was merely cross walked or selected by a CMS staff person some time ago. CMS should review the surveyed time and work and not compare it to the invalidated CMS-Other source of the current time and work. We urge CMS to accept a work RVU of 2.04 for CPT code 93623.**

Intracardiac Echocardiography (CPT Code 93662)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
93662	**Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure**	**1.44**	**2.53**

For the Intracardiac Echocardiography code (93662), CMS disagrees with the RUC recommended work RVU. CMS has proposed to decrease the work RVU from 2.53 to 1.44 for code 93662. CMS believes that their pick of an alternate work RVU more closely aligns with the valuation of this code than the RUC recommended. However, the RUC recommended work RVU for code 93662 is based on survey data. CMS should use valid survey data in establishing the work RVU for this code. The RUC thoroughly analyzed this code by review of history, survey data and magnitude estimation to other similar services.

For CPT code 93662, the RUC recommended the survey 25th percentile work RVU of 2.53. CMS disagrees with the RUC recommended work RVU of 2.53 and is proposing a work RVU of 1.44 for code 93662 based on the Agency's assumption that "significant decreases in time should be appropriately reflected in decreases to work RVUs." We disagree with CMS' proposed recommendation of 1.44 work RVUs for code 93662. The RUC recommended work RVU and time for code 93662 reflects the change in technology from when it was last valued in 2000. Intracardiac echocardiography has become an essential tool for complex catheter ablation of many types of arrhythmias and it has also enabled operators to significantly reduce the use of fluoroscopy. Since this service was last valued in 2000, arrhythmia mapping systems have developed the ability to incorporate intracardiac echo images into 3-dimensional electro-anatomical maps. This has improved the accuracy, safety, and effectiveness of catheter ablation for a wide range of arrhythmias, most notably atrial fibrillation. Additionally, the RUC's work RVU recommendation for code 93662 will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

CMS references code 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure*) (work RVU = 1.44 and 25 minutes of intra-service time) as a "good equivalent comparator code in light of the significant physician time reduction from 55 minutes" to 25 minutes in intra-service time for code 93662. CMS is incorrect in proposing the work RVU of 1.44 when referencing code 92979 because the nature of the services performed, intensity and work involved are different, with the two services performed in different parts of the heart for different reasons. Coronary IVUS is performed inside the coronary arteries to guide diagnostic catheterization and/or percutaneous coronary interventions.

Intracardiac Echocardiography (ICE) is used to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of a catheter location within the heart. It commonly guides trans-septal puncture—where the operator creates a hole in the septum of the heart to gain access to the other cardiac chambers on the other side of the heart—and is useful for early recognition of procedural complications, such as pericardial effusion or thrombus formation. ICE remains highly technical in nature and requires the patient to be anesthetized, which is not required in IVUS use. ICE is most used with atrial fibrillation ablations, a highly technical and challenging, and at times lengthy, procedure and is used throughout the entire procedure rather than just one point during the procedure.

The RUC recommendation for CPT code 93662 was based on the survey 25th percentile work RVU from robust survey results of 42 cardiologists as well as a favorable comparison to code 34713 *Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral (List separately in addition to code for primary procedure)* (work RVU = 2.50 and intra-service time of 20 minutes) and MPC code 36476 *Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)* (work RVU = 2.65 and intra-service time of 30 minutes). Both reference services bracket code 93662 in both physician work and time. **We strongly urge CMS to accept a work RVU of 2.53 for CPT code 93662.**

Quality Payment Program

HRS remains concerned that the Merit-Based Incentive Payment System (MIPS) continues to disincentivize meaningful participation by specialty physicians, including electrophysiologists. There are multiple aspects of the program that continue to limit direct engagement by our members, including:

- **The inability for clinicians to report measures as a sub-group.** MIPS does not have a mechanism that allows subgroups of specialists or subspecialists in multi-specialty TINs to report and be scored on measures that are most relevant to their practice. As a result, electrophysiologists in larger multi-specialty groups have limited control over the selection of which quality measures and which reporting mechanisms are best suited for their unique patient populations. While the virtual group participation option allows clinicians to come together across TINs, it does not address the need for sub-TIN reporting and is only available to small and solo practices. However, it does suggest that CMS can adopt more flexible policies related to sub-group reporting.

  Last year, CMS proposed the MIPS Value Pathways (MVP) framework, which aims to provide a more cohesive and simplified participation experience for clinicians by connecting measures and activities across the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population being cared for. Although CMS is proposing to delay implementation of this framework until at least 2022, it also proposes to update its guiding principles to emphasize that "MVPs will enhance comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups." We are encouraged by this proposal but remind CMS that the current program rules would have to be modified to allow for this type of reporting. HRS recommends that by allowing

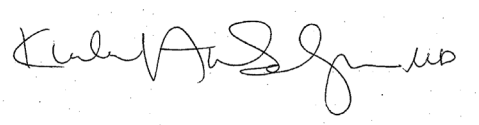
portions of a TIN to participate in MIPS collectively, multi-specialty practices could more comprehensively capture the range of services furnished by specialists in a group, which would result in more meaningful data for both clinicians and patients.

- **Scoring policies that disincentivize the uptake of more specialized measures**. CMS currently caps the number of performance achievement points that can be earned on measures that lack a benchmark, which disincentivizes the use of more specialized measures. When these more focused measures are not used, there is a chronic paucity of data to create benchmarks and the measure is eventually removed from the program in accordance with CMS policy. HRS invested significant resources to develop MIPS CQM #348: Implantable Cardioverter-Defibrillator (ICD) Complications Rate. However, in this rule, CMS proposes to remove this measure from the program in 2021, citing that "limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement [and the] limited adoption over multiple performance periods suggests this is not an important clinical topic for MIPS eligible clinicians." We believe that the justification for removing this measure is misguided since it fails to account for MIPS policies that inherently prevent this measure from being used. It also leaves cardiac electrophysiology with only two relevant measures in the Electrophysiology Specialty Set and discourages specialty societies from investing in the development of measures for use under this program. While HRS recognizes CMS' desire to simplify the MIPS measure inventory, we discourage that highly specialized measures that fill an important clinical gap, such as #348, are removed from the program. Electrophysiologists should have an opportunity to report the measure.

- HRS also is concerned that CMS is attempting to increase the MIPS performance threshold and tweak the performance category weights at a time when clinicians are struggling to keep up with the demands and expense of daily practice due to a pandemic. We strongly oppose CMS' proposal to increase the MIPS performance threshold in 2021 from 45 points to 50 points during this challenging time. We also oppose CMS' proposal to decrease the Quality category weight to 40%, while simultaneously increasing the Cost category weight to 20% since the pandemic has caused major disruptions in practice that will impact CMS' ability to accurately assess quality, and even more so, cost.

We look forward to your responses to these recommendations. For additional information, please contact Kimberley Moore, HRS's Director of Reimbursement and Regulatory Affairs at KMoore@hrsonline.org.

Sincerely,



Kimberly Selzman, MD, MPH, FHRS
Chair, HRS Health Policy Committee