September 11, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

*Submitted electronically via [www.regulations.gov](www.regulations.gov)*

RE: **Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS–1784–P)**

Dear Administrator Brooks-LaSure:

On behalf of the Heart Rhythm Society (HRS), I am writing to provide comments on the calendar year (CY) 2024 Medicare Physician Fee Schedule (PFS) 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 8,200 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health care professionals. Electrophysiology is a distinct specialty of cardiology, with certification in cardiology, as well as board certification in clinical cardiac electrophysiology through the American Board of Internal Medicine.

## Payment and Billing Provisions

### CY 2024 PFS Conversion Factor

The CY 2024 PFS estimates the conversion factor (CF) to be $ 32.7476, representing an approximate 3.4% across-the-board decrease from the current CF due to a zero percent update factor required under the *Medicare Access and CHIP Reauthorization Act of 2015* (*MACRA*), contraction of the temporary 2.50% positive adjustment authorized under the *Consolidation Appropriations Act, 2023* (CAA, 2023) to 1.25%, and a new budget neutrality adjustment of 2.17%, driven primarily by CMS' proposal to begin paying for the G2211 add-on code.

While we understand that some cuts are driven by statutory requirements, CMS fails to recognize that the PFS conversion factor has now decreased every year since 2020 and is now the lowest it has been since introduced in 1992. These continual PFS cuts will further stifle recovery and potentially dismantle individual EP practices for years. Congressional intervention is needed to avert the

statutory payment cuts to the PFS. **HRS strongly urges CMS to work with Congress to develop a permanent solution to stabilize the Medicare physician payment system for CY 2024 and beyond.** As discussed below, **HRS also urges CMS to mitigate the portion of the cut that is within its authority by rescinding the proposal to begin paying for the G2211 add-on code on January 1, 2024.**

**Valuation of Specific Codes**

**Phrenic Nerve Stimulation System (CPT codes 3X008, 3X009, 3X010, 3X011, 3X012, 3X013, 3X014, 3X015, 9X045, 9X046, 9X047 and 9X048)**

HRS supports CMS's proposal to accept the RUC-recommended work RVUs for eight new Category I CPT codes to describe insertion, repositioning, removal, removal and replacement of a phrenic nerve stimulator system, as well as adding four additional new Category I codes to describe activation, interrogation, and programming. These new codes will replace thirteen Category III codes, 0424T-0436T in CY 2024.

We also support CMS's proposal to refine the CA039 Post-operative visits (total time) for CPT code 3X014 from 36 minutes to 53 minutes to reflect that this code has a Level 4 office visit and not a Level 3 office visit included in its global period. In addition, CMS proposes to refine the equipment time for the exam table (EF023) from 36 minutes to 53 minutes for 3X014 to conform to the proposed change in clinical labor time. For all other codes, CMS proposes to accept the RUC-recommended direct PE inputs without refinement. **HRS urges CMS to finalize work and direct PE inputs for the family of codes for phrenic nerve stimulation system.**

**Remote Interrogation Device Evaluation – Cardiovascular (G2066, 93297 and 93298)**

HRS commends CMS for its decision to delete HCPCS code G2066, and accept the RUC-recommended direct PE inputs for CPT codes 93297 and 93298. Prior to the creation of G2066 as a contractor-priced service, the technical component for remote monitoring of implantable cardiac devices was reported with CPT code 93299. In 2018, HRS and the American College of Cardiology (ACC) administered a survey of 93297 and 93298 to establish technical component payment rate for the CY 2020 rulemaking cycle. Rather than adopt direct practice expense inputs at that time, CMS deleted 93299 and implemented G2066. Since implementation of G2066, payment rates have fluctuated across MAC regions, threatening the ability to provide safe and effective remote monitoring to high-risk patients with implantable cardiovascular physiologic monitoring systems and implantable loop recorder systems for arrhythmia diagnosis.

In reviewing the RUC-recommended direct PE inputs, a flaw was discovered in the formula and recommendation for equipment time. Specifically, the RUC recommended two changes to the inputs as follows:

- EQ198: Default formula adjusted to remove 11 minutes from CA021 because equipment would not be used while tech is educating/-re-educating the patient
- CA021: reduced by 7 minutes to 4 minutes for shorter education/re-education staff time

However, the recommendation spreadsheet formula for equipment captured BOTH the removal of the 11 minutes from the equipment formula AND the removal of the additional 7 minutes when clinical staff time was shortened. That approach reduces the equipment time for 93297 and 93298 by 18 minutes rather than 11 minutes.

For 93297, calculation for the equipment time for EQ198 should be 40 minutes, less the 7-minute reduction to clinical staff time, minus the remaining 4 minutes when staff is not using the equipment (40-7-4=29, rather than 40-11-7=22).

For 93298, the calculation should be 76 minutes, less the 7-minute reduction to clinical staff time, minus the remaining 4 minutes when staff is not using the equipment (76-7=69-4=65, rather than 76-11=65-7=58).

A request has already been sent to the RUC to adjust EQ198 by adding 7 minutes to correct this inadvertent double reduction. **We also request that CMS ensure the minutes are accurate prior to implementation of the direct practice expense inputs.**

Again, we commend CMS for proposing to delete G2066 and accept RUC-recommended direct practice expense inputs for the technical component of 93297 and 93298. We believe that national payment rates for the technical component for remote interrogation will stabilize payment for this life-saving service. **HRS urges CMS to finalize deletion of G2066 as proposed, and adopt direct practice expense inputs for 93297 and 93298.**

## Evaluation and Management (E/M) Services

### Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation (G2211)

In CY 2024, CMS is proposing to begin paying for office and outpatient E/M add-on code G2211 (*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 condition or a complex condition. (Add-on code, list separately in addition to office/ outpatient evaluation and management visit, new or established)*). This code was finalized in its current form during the CY 2020 PFS rulemaking cycle. However, this code was first introduced by CMS in a different iteration as part of CY 2019 rulemaking in conjunction with a policy to collapse the E/M visit levels. As part of that process, CMS listed the specialties in the code descriptor that were expected to be disadvantaged by the visit level collapse and for whom this code was originally designed. At that time, HRS opposed implementation of this policy.

CMS changed the CY 2019 version of the code, however, in each newly introduced version, the code would generate large, disruptive across-the-board cuts to the PFS conversion factor. In the CY 2021 PFS, CMS briefly discussed the previously finalized version of the add-on code (which was then referred to as GPC1X). In that discussion, 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:

> *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.*

As we stated at the time, HRS does not agree that this code is necessary. Within the E/M codes, additional work is recognized by billing a higher-level code, or when appropriate, applying a modifier. Including G2211 will cause significant confusion among physicians and billing professionals. Revising the outpatient E/M codes was intended to remove confusion.

We appreciate past and current 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's description above occurs outside the context of an office and outpatient E/M service, making the use of G2211 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 the code describes.

Congress recognized these problems and subsequently prohibited CMS from paying for the code for three years. While that prohibition ends at the end of this year, CMS has put forward the code with virtually no changes in response to Congressional concerns or the concerns previously voiced by stakeholders. **HRS remains opposed to the implementation of G2211 given the large cut it would make to electrophysiology services, many of which we continue to believe are already undervalued.** While we are still unconvinced of the vague rationales and valuation approach CMS has provided for G2211, regardless, CMS is directly cutting payments to electrophysiologists in order to pay for this code. For these reasons and because of the outsized impact the introduction of this code has on budget neutrality and the CY 2024 PFS conversion factor, **HRS urges CMS to rescind G2211.**

<u>**Request for Comment About Evaluating E/M Services More Regularly and Comprehensively**</u>

As part of a comment request included in this year's proposed rule, CMS states that it is generally seeking input on the descriptions, valuations, and inputs for paying for E/M services. As a part of this comment request, CMS poses questions about the value of the AMA RUC's input and whether other entities are better suited for these types of reviews.

**HRS continues to believe that the AMA CPT Editorial Panel and the RUC are the best-situated entities to provide input to CMS on values, documentation, and coding as a part of the annual PFS rulemaking cycle, including for E/M services.** We believe that the physician experts that provide input at all stages of defining codes and valuing services as part of the CPT and RUC continuum provide the essential clinical knowledge needed to conduct these functions. It also involves members from across the medical community, not just the specialty that delivers the service under review, to serve as a sounding board and safety net in defining and valuing codes.

HRS remains committed to providing expertise in those venues. At the same time, we are concerned that CMS attempts to marginalize the input of CPT and RUC, and may serve as a mechanism to reverse- engineer some other policy goal beyond providing medical expertise about the resources and work that are provided when furnishing a well-defined set of services. CMS is not bound by the recommendations of the RUC, and any stakeholder is free to establish the infrastructure to be able to generate detailed, data-driven recommendations for the valuation of services. We believe that CMS continues to consider RUC recommendations precisely because it provides the best available information and offers an unmatched coherent, data driven rationale to its recommendations. HRS will continue to support process improvements to address changes in the delivery of medical care and shifting resource use over time, but the RUC has provided the Agency with valuable information for setting reimbursements through the RBRVS as demonstrated quite publicly by the rate at which CMS accepts RUC recommendations.

**Split (or Shared) Services**

In the CY 2022 PFS final rule, CMS confirmed a policy for E/M visits in a facility setting (where "incident to" billing is not allowed) to allow visits furnished in part by a physician and a non-physician practitioner (NPP) to be paid based on which provider performs the "substantive portion" of the visit. The "substantive portion" is defined as more than half of the total time spent with the patient during the visit.

In some situations, while the physician will conduct the key elements of a visit, including medical decision making (MDM), the physician typically will not spend half of the time of the visit with the patient. HRS recognizes the importance of interdisciplinary heart rhythm teams including physicians and NPPs who collaborate on patient encounters that require history and physical examination as part of diagnostic assessment; management planning and execution; and careful communication with the patient for education and ensuring informed consent for procedures and other therapies. Because of these critical components of an encounter demand variable time expenditures that may not correlate with the full intensity and complexity the MDM process, HRS feels strongly that retaining the option to select the level of E/M visit based on MDM rather than the amount of time spent with the patient represents a more equitable and sustainable approach.

**While we appreciate the decision to delay implementation of the policy "through at least December 31, 2024" and continue to allow split and shared E/M visits to be selected based on time or the level of MDM, we are deeply concerned that basing the definition solely on which practitioner spends the most time with the patient will disadvantage physicians and disincentivize a team-based approach to patient care. We urge CMS to permanently modify the policy to allow E/M visits to be selected based on time or MDM**.

**Medicare Telehealth Policies**

CMS continues to develop policies that acknowledge the swift adoption of telehealth as the delivery mechanism for certain services during the COVID-19 pandemic. As part of this year's proposals, CMS proposes new categorization of services on the Approved List of Medicare Telehealth Services (i.e., services will be listed as "permanent" or "provisional"). As part of that CMS does not propose to set any specific timing for "provisional" service reevaluation because evidence generation may not align with a specific timeframe. **HRS appreciates the attention CMS has provided to**

**developing telehealth services as it continues to consider patient-focused policies that can help increase access to health care.**

CMS has shown a willingness to consider multiple approaches to maneuver the public health emergency and those flexibilities have produced a tremendous amount of value for the future of health care delivery. As CMS continues to develop its policies, **we encourage CMS to establish distinct policies for those services that are furnished via Category I telehealth (i.e., it is an otherwise face-to-face furnished service that happens to be delivered via telehealth) versus virtual services, which are inherently remotely delivered in their description and character.** We believe that for documentation, valuation, and program integrity reasons, it is important that CMS continue to make this distinction.

## Updates to the Quality Payment Program (QPP) Policies

### Merit-Based Incentive Payment System (MIPS) Performance Threshold

CMS proposes to increase the MIPS performance threshold from 75 points to 82 points for the CY 2024 performance period/CY 2026 payment year. The performance threshold is the minimum number of points a MIPS eligible clinician must score under the program to avoid a penalty. CMS must follow certain statutory requirements when setting the performance threshold each year. However, in the proposed rule, CMS proposes to adopt a revised interpretation of the methodology used to calculate the threshold, which is based on the mean final scores over a three-year period rather than a single prior year.

CMS estimates that an 82-point threshold for the 2024 performance year could result in 54% of clinicians receiving a penalty in 2026, with the average penalty being 2.4%. When Congress passed the *Medicare Access and CHIP Reauthorization Act of 2015* (*MACRA*), which included flat base payment updates, the intent was to provide physicians with the opportunity to fill in those payment gaps with value-based incentive payments. Subjecting such a large portion of physicians to payment cuts goes against the Congressional intent of *MACRA* and will pose a serious threat to practices at a time when physicians are already facing annual Medicare payment updates that are well below inflation, and fail to keep up with the cost of practicing medicine. This proposal also does not account for the ongoing effects of COVID-19 on the healthcare system, including staffing shortages, disrupted patient volumes, and residual strains on resources that make it more challenging to comply with MIPS and potentially distort performance data.

Finally, we remind CMS that numerous clinicians were excepted from MIPS since the 2019 performance year due to a COVID-19 hardship. Assuming that the hardship exception is no longer offered in 2024, these clinicians will be re-entering the program faced with a drastically higher bar in terms of the performance threshold, the inventory of measures, and reporting and scoring requirements. **Overall, we do not believe that increasing the performance threshold at this time will have any positive effect on quality and if anything, could further strain practices that are in the greatest need of additional resources to support investments in high quality care. For these reasons, HRS strongly opposes an increase in the MIPS performance threshold at this time.**

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**Advancing Care for Heart Disease MIPS Value Pathways (MVP)**
CMS proposes modifications to the previously finalized Advancing Care for Heart Disease MVP. HRS supports CMS' proposal to add quality measures specific to cardiology and advancing health equity to this MVP for CY 2024, including:

- Q006: *Coronary Artery Disease (CAD): Antiplatelet Therapy*
- Q118: *Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)*
- Q487: *Screening for Social Drivers of Health*

As we expressed last year when CMS proposed to add quality measures encompassing the clinical care of electrophysiology, we support the availability of additional measures that help to capture a more complete picture of quality care for patients who are at risk of, or have, heart disease. These additional measure options will also provide clinicians with more flexibility to best meet the needs of their unique patient population. **HRS urges CMS to finalize its proposal to add the aforementioned quality measures to the Advancing Care for Heart Disease MVP.**

**Qualifying Participants (QP) in Advanced APMs**
CMS is required by statute to set specific thresholds for becoming a QP that account for the amount of Medicare payments received, or Medicare patients seen, through an Advanced Alternative Payment Model (APM). To date, clinicians who earn QP status have been eligible for an APM incentive payment and are exempt from MIPS. Under statute, the threshold percentages are set to increase, beginning with the 2024 performance year/2026 payment year as follows:

- Medicare payments: QP threshold increasing from 50% to 75%
- Medicare patients: QP threshold increasing from 35% to 50%

Also under statute, eligible clinicians who are QPs for the 2023 performance year will receive a 3.5% lump sum APM incentive payment in the 2025 payment year (down from 5% in prior years). Beginning with the 2024 performance year/2026 payment year, the lump sum incentive payment goes away and QPs will instead receive a slightly higher PFS payment rate update (calculated using a higher "qualifying APM conversion factor") of 0.75% versus non-QPs (including MIPS participants) who will receive 0.25% update. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

**Although we understand that CMS must comply with these statutory requirements, HRS is very concerned about the negative impact that these changes will have on our members' eligibility for the QP track and the general movement of our specialists into APMs.** Specialists in cardiac pacing and electrophysiology have had few opportunities to meaningfully participate in Advanced APMs, and to qualify as QPs to date since most existing models are primary care or population-focused, and provide no meaningful role for more specialized practitioners.

We appreciate CMS's attempt to propose policies aimed at ensuring that specialists are not excluded from Advanced APM participant lists and therefore, ineligible for QP status. For example, CMS proposes to make QP determinations at the individual eligible clinician level instead of at the APM Entity level. It also proposes to change the definition of "attribution-eligible beneficiary" to include any beneficiary who has received a covered professional service furnished by the eligible clinician rather than relying strictly on E/M services as the default for attribution for purposes of QP determinations.

Nevertheless, we are concerned that the positive intent of these policies will be lost if implemented alongside increasing QP thresholds, which will make it even more challenging for specialists to qualify as QPs at the individual level next year. **While we would like to see a Congressional solution that gives CMS the flexibility to set QP thresholds at a more reasonable level, in the interim, we request that CMS apply both individual-level and APM Entity-level QP determinations and apply the more favorable determination starting in CY 2024. We also urge CMS to provide more data on QP eligibility among specialists and to closely monitor the impact of QP and other APM track policies on specific types of practices and patient populations.**

**HRS also encourages CMS to work with Congress to make technical updates to MACRA that extends the 5% incentive payment for QPs in Advanced APMs to ensure physicians have the resources to support robust engagement in APMs. We also request that CMS work more closely with specialty societies like HRS to develop and test more specialty-focused APMs that are meaningful to our members and patients.** As noted earlier, many of our members have not even had the opportunity to qualify for the 5% incentive payment and continue to face Medicare payment updates below inflation that make it challenging to invest in APMs.

<u>Appropriate Use Criteria for Advanced Diagnostic Imaging Program</u>

**HRS strongly supports CMS proposal to pause implementation of the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging program and to rescind the current AUC program regulations.** This program, authorized through legislation in 2014, would have required clinicians ordering advanced diagnostic imaging services to consult AUC via a clinical decision support tool and communicate those results to the furnishing clinician for payment purposes. Ultimately, the program set out to require prior authorization for clinicians found to be outliers in terms of inappropriate ordering.

Although HRS strongly supports efforts to identify and minimize inappropriate care, the AUC Program has faced insurmountable implementation challenges since its enactment. Over the years, other initiatives have been adopted that target similar goals, including the enactment of the *MACRA* and the rise of new health care payment and delivery models that hold clinicians responsible for health care resource use, such as APMs and MIPS. We are pleased that CMS recognizes the waning need for this administratively challenging program and look forward to collaborating with CMS to further its goals through other existing programs.

**Conclusion**

Once again, HRS appreciates the opportunity to offer comments on the proposed rule for the Medicare Physician Fee Schedule and other Part B programs for CY 2024. If you have any questions or would like to discuss our comments, please contact Lisa Miller, MS, Senior Director of Health Policy and Reimbursement at lmiller@hrsonline.org or (202) 464-3413.

Sincerely,

Jodie L. Hurwitz, MD, FHRS
President, Heart Rhythm Society