September 9, 2024

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

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

Dear Administrator Brooks-LaSure:

On behalf of the Heart Rhythm Society (HRS), I am writing to provide comments on the calendar year (CY) 2025 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 8,700 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health care professionals. Electrophysiology is a distinct specialty of cardiology, with board certification in cardiology, as well as in clinical cardiac electrophysiology through the American Board of Internal Medicine.

We appreciate the opportunity to share our position on several portions of the CY 2025 proposed rule. However, we also wish to make a general request regarding the impact of the payment provisions and the quality reporting requirements on electrophysiologists. Effective in April 2011, the Centers for Medicare & Medicaid Services (CMS) created a specialty enrollment designation (21) for cardiac electrophysiologists in response to the request of HRS. We remain appreciative of this decision. While we understand that some time needed to pass before use of the specialty designation proliferated broadly enough to enable more granular reporting of CMS data and estimates feasible for electrophysiology, we request that CMS start to regularly include cardiac electrophysiology in its rulemaking activities. For instance, even though specialty enrollment code 21 has been available since 2011, CMS failed to include cardiac electrophysiology in the CY 2025 PFS proposed rule TABLE 128: CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty. Therefore, **HRS urges CMS to regularly report specialty-specific data and projections with the inclusion of specialty designation code 21- cardiac electrophysiology.**

Payment & Billing Proposals

CY 2025 Conversion Factor

CMS estimates the CY 2025 conversion factor (CF) to be $32.3562, representing an approximate 2.8% 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), the elimination of the temporary 2.93% positive adjustment authorized under the *Consolidation Appropriations Act, 2024* (CAA, 2023), and a budget neutrality adjustment of +0.05%.

While we understand that that the 2025 vs. 2024 cut is technically based on 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 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 2025 and beyond**. These yearly reimbursement cuts to services for Medicare patients threaten patient access to care, drive mass consolidation of physician practices, and undermine the ability of practices to shift toward value-based models of care and payment. This practice of continually cutting the reimbursements of electrophysiologists for care delivered to Medicare beneficiaries is, quite frankly, unsustainable as recognized by the trustees of the Medicare trust funds.[1]

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

General 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. **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**. Given that maintaining this level of access to care via telehealth is dependent on Congressional extension of the waiver of the telehealth geographic and originating site requirements, **HRS also urges CMS to work with Congress to ensure that the flexibilities are permanently extended beyond the December 31, 2024, deadline**.

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 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.

[1] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, p. 189 (May 6, 2024).

CMS Proposal on Use of Audio-only Technology to Furnish Services via Telehealth

Federal statute requires that, in order to be paid by Medicare, a telehealth service be furnished via a "telecommunications system." CMS currently defines "interactive telecommunications system" for purposes of its telehealth coverage and payment policy as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner."

Through the course of Congressionally-expanded telehealth coverage, certain services (e.g. mental health services) are allowed to be provided by physicians or practitioners via audio-only services to patients when located in their homes. Through its experience with this coverage, CMS believes it is appropriate to broaden the availability of audio-only telecommunication systems when patients are located in their home receiving a telehealth service in certain circumstances. Therefore, CMS proposes that an "interactive telecommunications system" may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology. **HRS encourages CMS to finalize this policy, but we note that this will have limited applicability on the ability of electrophysiologists to provide telehealth services to Medicare beneficiaries if Congress does not extend the waivers that allow patients to receive services furnished via telehealth in their homes past the December 31, 2024, sunset of the waivers.**

Strategies for Improving Global Surgery Payment Accuracy

Transfer-of-Care Modifiers

CMS reviewed the existing transfer-of-care modifiers to be reported when a formal transfer-of-care arrangement is documented by both the proceduralist and another practitioner providing the related post-operative visits. CMS states that "these modifiers are required to be appended to the relevant global package code when billing for services that are within the scope of the global package (within the global period and related to the surgical procedure) only when the proceduralist and one or more other practitioners who are not in the same group practice as the proceduralist formally document their agreement to provide distinct portions of the global package."

The current transfer-of-care modifiers for global surgical packages are:

- Modifier ~54 (*Surgical Care Only*)
- Modifier ~55 (*Post-Operative Management Only*)
- Modifier ~56 (*Pre-Operative Management Only*)

The use of these modifiers updates payments for the CPT global code billed according to the percentages in relative value files associated with the portion of care identified with the modifier (e.g. post-operative management only). CMS proposes to broaden the use of these modifiers with respect to all 90-day global surgical packages beyond scenarios where there is a formal, documented transfer-of-care to include also an "informal, non-documented but expected, transfer of care." **HRS supports efforts to maintain the accuracy of the values of services paid under the Medicare physician**

fee schedule, but we fail to see the utility of this proposal and how it would produce any usable information for CMS in its efforts to improve the accuracy of 90-day global codes.

First, as electrophysiologists, we are firmly committed to high quality, coordinated care for patients with heart rhythm disorders. We hope that CMS is not suggesting via this policy that electrophysiologists do not care for their patients outside of the event of the procedure itself. Second, we have significant questions about what an "informal, non-documented but expected, transfer of care" is. For services with a 90 day global designation delivered by an electrophysiologist, it is hard to envision an "expected" transfer of care that is informal and without documentation (to a professional outside of the group practice of the electrophysiologist that performed the procedure) that would result in the use of this modifier under the proposed revised guidance. While we believe it is possible that this expanded policy for use of transfer-of-care modifiers will not result in much change in utilization of Modifier ~54 (*Surgical Care Only*) because "informal, non-documented but expected" transfers-of-care would seem to be rare, we wonder, then, why CMS has proposed this change.

If, on the other hand, CMS believes that this policy will result in an increase of the use of Modifier ~55 (*Post-operative Management Only*), we are perplexed by the lack of discussion about how to properly append Modifier ~55 outside of a formal transfer-of-care and why CMS would abandon policies it has supported in recent years to coordinate care by instead now encouraging physicians to take over post-procedure management "informally" perhaps in some instances without communicating with the physician who performed the procedure at all. In addition, the reference to "expected" in the CMS proposal should have no impact on the utilization rates of Modifier ~55 because Modifier ~55 should not be appended to a claim unless post-operative management of patient care has *actually* occurred.

In sum, **HRS is confused by CMS' policy to expand the use of transfer-of-care modifiers to an "informal, non-documented but expected transfer-of-care" and expresses concern about the ability of CMS to extrapolate any meaningful data for purposes of updating global code values based on changes in utilization of the transfer-of-care modifiers if this policy is finalized.**

Post-op Care Services Add-on Code

CMS states that it is aware of "instances where post-operative care is not furnished by the proceduralist or another practitioner in the same group practice, or even by a practitioner who is in the same specialty as the proceduralist despite there being no formal transfer of care" and that "there is an extra level of complexity involved when a practitioner sees a patient post-operatively after a surgical procedure performed by another practitioner in those circumstances" Therefore, for CY 2025, CMS is proposing an office and outpatient E/M visit add-on code, GPOC1, "that would account for resources involved in post-operative care for a global surgical package provided by a practitioner who did not furnish the surgical procedure and does not have the benefit of a formal transfer of care." CMS is proposing a work RVU of 0.16 for GPOC1 with 5.5 minutes of work time and no direct PE inputs.

First, HRS would like to reiterate on behalf of our members that electrophysiologists take care of their patients. In the U.S. it takes approximately 12 years of medical training to become a board certified cardiac electrophysiologist, starting with medical school, followed by a residency and fellowship in internal medicine and cardiology, and an additional two-years of training in cardiac electrophysiology. Therefore, it is unrealistic to believe that by proposing to create add-on code GPOC1 for transfer of

post-op care with a work value of 5.5 minutes, that patients with heart rhythm disorders can casually be treated by non-electrophysiologists or even non-cardiologists and that a physician without training for treatment of heart arrhythmias can comprehensively research appropriate post-procedure care for a patient who has been treated for an arrhythmia.

HRS opposes the implementation of GPOCI out of concern for the care of our patients, the liability implications for non-specialists treating patients for post-procedure care when they did not perform (and do not understand as made clear by the code descriptor itself) the procedure, and the assumptions by CMS that physicians with no experience or knowledge of electrophysiology can assess a patient who has had a procedure performed by an electrophysiologist and appropriately guide the patient through the complications and warning signs following, for instance, a cardiac ablation. At the very least, we believe the CMS needs to address at length the following questions:

- If the add-on code is finalized, how will CMS be able to tell that the E/M visit is directly related to the 90-day global procedure (and not coincidental to some other reason for the E/M visit)? What program integrity protections will CMS put into place to ensure that the add-on code is not used only because a physician sees a patient who is in a global period, but the visit is not directly a post-op visit?
- If the add-on code is finalized, how does CMS intend to define "a different specialty than the practitioner who performed the procedure" given specialty and related sub-specialty designations? As mentioned at the beginning of our comment letter, cardiac electrophysiologists have their own Medicare enrollment specialty designation. Would a cardiologist (in a different group practice) who sees a patient after, for example, a cardiac ablation performed by an electrophysiologist be able to bill GPOCI?

We are extremely concerned that this add-on code is poorly defined, subject to abuse, and likely to generate claims data that CMS will misappropriate to suggest that physicians who did not perform the global procedure are performing post-op visits when (a) they are not, in fact, actual visits related to post-operative care for the procedure; and (b) non-responsive to whether the physician who performed the procedure is delivering post-operative care because there will be no competing claims data given that the care is being delivered inside the global period (and thus no claims are submitted). For all of the reasons listed above, HRS opposes the implementation of GPOC1.

Quality Payment Program (QPP) Proposals

Request for Information (RFI): Transforming the Quality Payment Program

Through this RFI, CMS seeks input on clinician readiness to transition fully to Merit-Based Incentive Payment System (MIPS) Value Pathways (MVPs) as CMS contemplates sunsetting traditional MIPS and require MVP reporting by 2029. **While HRS supports the goals of MVPs—including the need to streamline MIPS reporting requirements and to make reporting and participation in MIPS more relevant and meaningful for specific specialties, medical conditions, and patient populations— we oppose making it a mandatory pathway until CMS first addresses other issues with the program, such as the limited measure inventory and scoring policies that disincentivize the use of more specialized measures**.

We remind CMS that the Electrophysiology Cardiac Specialist specialty measure set only includes two quality measures. Under traditional MIPS, electrophysiologists are only required to report on those two measures, whereas under MVPs, they would be required to identify four measures to report. Currently, under the voluntary MVP framework, if a clinician cannot identify four relevant measures, they cannot participate in an MVP, but still have the option to participate in traditional MIPS. We are concerned that if CMS makes MVPs mandatory, without first addressing specialties that continue to have limited measures, our members would be forced to report on measures that are not directly relevant to their practice or else face a potential penalty.

Merit-Based Incentive Payment System (MIPS) Performance Threshold

CMS proposes to maintain the threshold to avoid a penalty under the MIPS program of up to nine percent at 75 points for the CY 2025 performance year/2027 payment year. **HRS supports CMS' decision to not increase the MIPS performance threshold and appreciates CMS taking into account the need for program consistency, the need to allow clinicians to gain more experience with cost measure scoring, and the ongoing disruptions to practice resources and MIPS data caused by the COVID-19 pandemic and Change Healthcare cyberattack.**

Substantive Changes to MIPS Quality Measures

CMS proposes substantive changes to measure #393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision. The update would clarify the definition of a new device so that a new device would be "either the first device OR a device implanted with new functionality." **HRS supports the update to the measure instructions. We agree with CMS' rationale that the change would ensure alignment and consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates. We urge the agency to finalize the change as proposed.**

Scoring for Topped Out Measures in Specialty Measure Sets with Limited Measure Choice

CMS proposes to modify the manner in which it scores topped out measures by selectively removing the 7-point topped out scoring cap for measures related to specialties with limited measure choice and scoring potential. While HRS supports this proposal in concept, it would not currently benefit our specialty. As we noted earlier, there are only two measures in the Electrophysiology Cardiac Specialist specialty measure set. These two important measures have been in the program for at least five years, yet they continue to lack a benchmark. Since measures without a benchmark are now worth 0 points, there is no incentive for our members or the institutions they work in to select the measures for reporting, and accrue the data needed to develop a benchmark. This results in a never-ending cycle where the measures remain stuck without a benchmark.

CMS has expressed hope that clinicians will start to use these measures as they transition into more specialized reporting using MVPs. However, if these measures still earn only 0 points under the MVP framework, then few clinicians will want to take the risk to report them. CMS also recently finalized a scoring policy to incentivize reporting of brand-new measures (i.e., subjecting them to a scoring floor in their first and second years in the program). Unfortunately, this policy does not address measures that have been sitting in the program for many years without a benchmark, such as our measures. **HRS urges CMS to adopt a policy that extends incentives to measures that have been in the program for a certain number of years, but continue to lack a benchmark. For example, CMS could grandfather these non-benchmarked measures into the new measure scoring policy for**

at least two years to determine whether the current scoring limitations are contributing to their lack of uptake.

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, following numerous Congressional extensions, beginning with the 2025 performance year/2027 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, this incentive payment drops to 1.88%, while QPs will also start to 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. Beginning with the 2025 performance year/2027 payment year, the APM incentive payment goes away, and QPs are only eligible to receive the higher qualifying APM conversion factor going forward. Throughout this time, 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 remains 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, particularly 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 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. **HRS would like to see a Congressional solution that gives CMS the flexibility to set QP thresholds at a more reasonable level, but in the interim, we support CMS' proposal to broaden the definition of "attribution-eligible beneficiary" for purposes of QP threshold determinations. We also urge CMS to provide more data on QP eligibility broken down by specialty 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 to extend 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.

RFI: Building Upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

CMS is considering a model design that would increase the engagement of specialists in value-based payment and encourage specialty care provider engagement with primary care providers and beneficiaries. This model, which would be geared toward specialists in ambulatory settings, would leverage the MVP framework. CMS expects this potentially mandatory ambulatory specialty model would be implemented no earlier than 2026, ensuring participants have sufficient time to prepare for the model.

As HRS alluded to earlier in this letter, MVPs are not yet constructed in a manner that can accurately capture and drive improvements in value, particularly for electrophysiologists. Since MVPs carry forward most of the problematic features of MIPS— including limited measure sets, siloed performance categories, and scoring rules that disincentivize the use of more focused measures—they do not offer a solution for specialties like electrophysiology that lack meaningful pathways into APMs. This model, as contemplated, would also focus on ambulatory settings and not offer a solution for hospital-based specialists that have not been able to participate meaningfully in current models to date. **HRS urges CMS to address the ongoing lack of specialty-focused APMs through more comprehensive and focused solutions that support better coordination of care and more accurate assessments of value.**

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 2025. 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,

Kenneth A. Ellenbogen, MD, FHRS
President, Heart Rhythm Society