

February 10, 2025

Stephanie Carlton
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Re: Potentially Misvalued Code, CPT 93296

Submitted electronically via MedicarePhysicianFeeSchedule@cms.hhs.gov.

Dear Acting Administrator Carlton:

The undersigned Independent Diagnostic Testing Facilities (IDTFs) are writing to request that CMS update the direct practice expense inputs and calculation of PE RVUs for the cardiac remote interrogation device evaluation service described by Healthcare Common Procedure Coding System (HCPCS) Code 93296 for CY 2026, and in the alternative, that CMS nominate HCPCS Code 93296 for review under CMS's potentially misvalued services initiative because the service has "experienced substantial changes in PE." As we explain in more detail below, we are very concerned that current direct practice expense inputs assigned to this technical service code nine (9) years ago do not accurately reflect the current standard of care and direct practice expense resources involved to furnish the service. We feel strongly that this code is misvalued and that an underlying resource input review for this code is urgently necessary. As IDTFs, we are proud to be working on the front lines to provide these critical cardiac diagnostic services to Medicare beneficiaries located throughout the country.

Background – HCPCS Code 93296

HCPCS Code 93296 is a technical component (TC) code that is defined as *remote interrogation device evaluation, up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*.

Stated simply, this service facilitates comprehensive remote interrogation of implanted cardiac defibrillators and pacemakers, which is critical to diagnosing and caring for Medicare patients with complex cardiac issues. The service includes receipt and review of device data and subsequent communication with patients about their device status and functionality, and distribution of results to the patient's treating physician. Effective remote monitoring, including that provided under HCPCS 93296, enhances patient outcomes by enabling timely adjustments to device settings and rapid responses to cardiac abnormalities. This proactive healthcare

delivery reduces emergency visits and hospitalizations, thereby decreasing overall healthcare costs and ensuring equity in healthcare delivery, especially in remote or underserved areas.¹

Medicare's approved direct costs for HCPCS code 93296 were last reviewed by the AMA RUC and recommended to CMS in 2016, and were approved and implemented by CMS for the 2018 payment year. Since 2016, the technology and requirements to provide the services represented by 93296 have increased significantly as outlined in the below referenced evidence-based expert consensus statement, resulting in concomitant increases in the direct costs of performing these services, which we believe requires a corresponding adjustment to the direct costs for HCPCS Code 93296. Indeed, Section 1848(c)(2)(K)(ii) of the Social Security Act specifically directs the Secretary to examine potentially misvalued codes where there are "substantial changes in practice expenses."²

Background – Increased Direct Resource Requirements for 93296 Services

The 2023 Heart Rhythm Society/European Heart Rhythm Association/Asia Pacific Heart Rhythm Society/Latin American Heart Rhythm Society expert consensus statement on practical management of the remote device clinic ("Consensus Statement") details the importance of remote diagnostic monitoring care.³ The Consensus Statement recognizes changes in the clinical requirements for our IDTFs and all providers of remote diagnostic cardiac monitoring services including those described under HCPCS Code 93296. The Consensus Statement emphasizes the added workload of remote monitoring such as "triaging and reviewing frequent remote transmissions, and timely management of alerts,"⁴ as well as additional engagement with patients, including increased patient education and expedited timelines to respond to device problems.

Our review of the existing inputs assigned to HCPCS Code 93296 finds that the current non-physician clinical labor times, clinical labor type, and equipment cost insufficiently state the direct resources incurred to provide this remote interrogation device evaluation service, and require correction as detailed below.

As further described in the Consensus Statement, we have identified the following considerations that are not accurately reflected in the valuation for HCPCS 93296:

- **Underestimation of Complexity:** The direct practice expense resource inputs for CPT 93296 needs to accurately reflect the complexity and clinical responsibility associated with the ongoing management of critical cardiac devices. The services require advanced technology and specialized clinical expertise, leading to substantial operational costs.

¹ Aileen M. Ferrick et al., 2023 HRS/EHRA/APHRS/LAHRs Expert Consensus Statement on Practical Management of the Remote Device Clinic (2023), https://www.hrsonline.org/guidance/clinical-resources/2023-hrsehraaphrslahrs-expert-consensus-statement-practical-management-remote-device-clinic?gad_source=1&gclid=Cj0KCCQIAkoe9BhDYARIsAH85cDOusU-vRRcEnwoXzUmN2COkX0_DiRVHuOM8cYMf8riBNXW-KrFagnAaAs5NEALw_wcB.

² 42 U.S.C. 1395w-4(c)(2)(K)(ii)(II).

³ Ferrick et al., *supra* n.1.

⁴ *Id.* at 10.

This complexity has increased as the number and type of alerts able to be offered to patients has increased.⁵ The Consensus Statement states that providers “require robust organizational models and processes in place to safely manage alerts and workload.”⁶

- **Technological Advancements:** Innovations in device technology have significantly increased the volume and complexity of data these devices generate, requiring more skilled clinical labor and extended time for data analysis. “The growth of [remote monitoring] and [remote monitoring] transmissions has been accompanied by an exponential increase in work-load.”⁷
- **Critical Patient Management:** The management of patients with, and the analysis of the information obtained from, these devices directly impacts a physician’s treatment plans and outcomes, necessitating frequent, thorough reviews and timely interventions. The Consensus Statement recommends that the number of clinical staff and the time clinical staff need to perform responsibilities must be increased to improve patient management.⁸
- **Shift to More Frequent Monitoring:** Historically, interrogation of the device through remote monitoring might have occurred once every 90 days, but there has been a significant shift towards more regular interrogation and monitoring. This transition underscores the evolution of monitoring as a recognized Class 1A standard of care. Regular interrogation and monitoring provides for immediate detection and response to cardiac events, significantly enhancing patient safety and treatment efficacy. The daily volume of data generated for remote monitoring has increased significantly.⁹
- **Resource Utilization:** The resources utilized in remote monitoring, including direct clinical systems as well as clinical software tied to the hardware and technology maintenance, have increased over time consistent with the clinical requirements for these services. Recognizing the increase in resource utilization is essential for fair and accurate valuation. The Consensus Statement cites one study that found that each remote monitoring transmission resulted in 32 tasks to completely manage a patient, such as transmission review and diagnosis, charting and billing, and triage and scheduling.¹⁰ These higher volumes require new mechanisms to assign priority levels to reviews of incoming data.¹¹

93296 Direct Costs

HCPCS Code 93296’s direct cost inputs for clinical labor and equipment do not reflect the current direct costs incurred to furnish the services. The currently approved clinical labor rate per minute for HCPCS Code 93296 is \$0.44 (the CMS rate assigned to Electrodiagnostic

⁵ *Id.* at 40.

⁶ *Id.* at 40.

⁷ *Id.* at 13.

⁸ *Id.* at 4.

⁹ *Id.* at 5.

¹⁰ *Id.* at 19.

¹¹ *Id.* at 4.

Technologists, L037A) and the currently approved clinical labor time is 28 minutes, resulting in a clinical labor direct cost of \$12.32. Further, the current CMS assigned price for the equipment is \$123,250 (CMS price assigned to pacemaker interrogation, system, EQ320) resulting in an equipment direct cost of \$13.08. The supply costs for HCPCS 93296 are minimal. The total direct cost assigned by CMS to HCPCS Code 93296 is \$25.84. The 2025 national reimbursement for 93296 is \$19.41. The current direct practice expense resource inputs and valuation does not reflect the change in the types of clinical staff and equipment that are involved in furnishing this technical service and that have been previously approved by CMS for other similar implantable device diagnostic services.

We engaged Health Management Associates (HMA) to conduct a direct practice expense input assessment among the IDTF suppliers of this service signed below. We requested HMA to serve as an independent third party to confidentially and objectively collect resource input information from the participating IDTFs focusing on non-physician clinical labor. The below are estimates of the typical clinical labor based on the responses received from the IDTFs. A standardized data collection template was utilized to collect input information and 2023 volume and device mix from the participating IDTFs. This information was used to develop a consensus input recommendation. The findings are volume-weighted and reflect the mix of pacemaker and ICD services reported by the IDTFs and provided under HCPCS 93296. We believe the methodology and direct cost estimates from this exercise are credible, valid, and support the need to review the underlying inputs assigned to 93296.

Non-Physician Clinical Labor Findings: 93296

Based on the information submitted by the participating IDTFs, the total non-physician clinical labor time required to complete the tasks necessary to furnish remote interrogation device evaluation up to 90 days is 83.66 minutes,¹² as detailed here: Patient enrollment and verification (0.08 minutes), patient education and consent (0.90 minutes), device preparation and setup (3.20 minutes), data review and analysis (25.25 minutes), unscheduled event and episode evaluation (8.70 minutes), unscheduled alert management and reporting (21.84 minutes), unscheduled transmission data archival and documentation (1.46 minutes), scheduled summary report preparation and delivery (6.17 minutes), patient support and inquiry response (2.96 minutes), manual transmission and connectivity management (3.47 minutes), and quality assurance of alert and routine reports (9.63 minutes).¹³ Thus, the objective consensus input information from the participating IDTFs supports the need to update the direct practice expense inputs associated with this service, or alternatively, to review the underlying resource inputs through the misvalued services initiative, and illustrates a significant increase in clinical labor time from the 28-minutes

¹² This total time was calculated by volume-weighting the two diagnostic services represented by CPT Code 93296. The survey results indicated slightly different clinical labor times of 81 minutes for pacemakers and 89 minutes for implantable cardioverter defibrillators (ICDs). We will follow up separately with a full report detailing our findings.

¹³ This conservative estimate includes only tasks consistently provided across IDTFs and that are clearly clinical services. Some IDTFs reported providing various additional monitoring, technical support, patient re-education, patient discharge, and other activities, which HMA determined were not clinical and thus were not included in clinical staff time.

currently approved by CMS. Increasing clinical labor minutes for HCPCS 93296 is critical to ensuring that accurate direct resource inputs are incorporated into valuation for remote interrogation device services reported under HCPCS 93296.

Further, the clinical labor type that is utilized for these services is different than is currently reflected by CMS. The labor rate assigned to HCPCS 93296 is currently based on electrodiagnostic technologists (L037A) providing the service, which have an approved rate of 44 cents per minute. However, cardiovascular technicians (L038B) are the accurate non physician clinical labor staff type that are used by IDTFs (CMS approved rate of 60 cents per minute) to provide this service. The change to the cardiovascular technician (L038B) would also ensure 93296 is consistent with other implantable device monitoring services utilized by these same providers.¹⁴

Equipment Findings: 93296

The minutes per use in the equipment cost formula should also be updated to reflect the updated clinical labor time associated with remote interrogation device evaluation for purposes of calculating an itemized equipment cost per the CMS formula. Further, the equipment assigned to 93296 is currently “pacemaker interrogation, system” (EQ320), which is priced at \$123,250. Other implantable device codes, such as the technical component of HCPCS 93297 and 93298, are assigned “pacemaker follow-up system (including software and hardware)” (EQ198), which is priced at \$279,453. A price of \$279,453 better reflects the average cost of the ICD/pacemaker system equipment. It is also consistent with the CMS accepted equipment cost for other implantable device services provided by these same providers.¹⁵ In fact, the IDTFs use this same system to provide the services represented by HCPCS 93296. The equipment component of direct costs for HCPCS 93296 are currently significantly undervalued and should be updated. Updating the equipment purchase price and time in use consistent with the updated non physician clinical labor time will help assure a more accurate resource-based valuation of this service.

We respectfully request CMS update the direct practice expense inputs assigned to HCPCS 93296 or, alternatively, designate the service as potentially misvalued to initiate review of the code.

Thank you for considering our recommendations. Please contact Jennifer Walsh at JWalsh@foley.com if you would like to discuss these recommendations or should you require clarification or further information.

¹⁴ See discussion of technician type and equipment cost for implantable device monitoring services (HCPCS 93297 and 93298) in 2024 PFS Final Rule: Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 Fed. Reg. 78,818, 78,913 (Nov. 16, 2023).

¹⁵ *Id.*

Sincerely,

Cardiac RMS

EquiMed

IronRod Health

Rhythm Management Group

Vector Remote

cc:

Ryan Howe, Director, Hospital & Ambulatory Policy Group, ryan.howe@cms.hhs.gov;

Gift Tee, Deputy Director, Hospital & Ambulatory Policy Group, gift.tee@cms.hhs.gov;

Lindsey Baldwin, Director, Division of Practitioner Services, lindsey.baldwin@cms.hhs.gov