June 9, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–1849–P
P.O. Box 8010
Baltimore, MD 21244–8013

Submitted electronically via www.regulations.gov

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1849-P)

Dear Administrator Oz:

On behalf of the Heart Rhythm Society (HRS), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) on the Inpatient Prospective Payment System (IPPS) proposed rule for fiscal year (FY) 2027. HRS (hereinafter referred to as the Society) represents more than 9,600 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health care professionals. Electrophysiology is a distinct specialty of cardiology that includes board certification in cardiology, as well as in clinical cardiac electrophysiology, through the American Board of Internal Medicine.

General IPPS Payment Update and Changes to Specific MS-DRG Classifications

Based on the rate setting processes, CMS proposes to increase the FY 2026 IPPS standardized amount of $6,752.61 to $6,967.87 for FY 2027. We support the increase of approximately 3% for hospital inpatient services given the continued rising costs of delivering care and the increased complexity of patients needing care in the hospital setting. We also highlight and support that many of the MS-DRGs to which cardiac electrophysiology inpatient cases are assigned would experience additional increases if the standardized amount is finalized. This includes payments for cases assigned to the following MS-DRGs:

- MS-DRG 273 (*Percutaneous Intracardiac Procedures with MCC*)
- MS-DRG 274 (*Percutaneous Intracardiac Procedures without MCC*)
- MS-DRG 278 (*Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC*)

- MS-DRG 279 (*Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures without MCC*)
- MS-DRG 317 (*Concomitant Left Atrial Appendage Closure and Cardiac Ablation*)

As enhanced complexity and co-morbidities in patients requiring inpatient electrophysiology services continue to increase, ***we urge CMS to finalize the MS-DRG changes for FY 2027.***

To adequately resource hospital systems to improve patient access to care, facility level payments must be paired with inflation-based updates to physician payments for professional services. Under the Medicare Physician Fee Schedule (MPFS), physician payment has eroded dramatically over the past two decades, even as the costs of running a medical practice have continued to rise. Physicians are the only Medicare providers that do not receive an annual payment update tied to inflation. The persistent payment cuts have real consequences for patient access to physician services in the facility and office settings. While we understand that the MPFS is a separately legislated vehicle from the IPPS, ***we urge CMS to work with Congress to modify the MPFS annual payment update to reflect the increasing costs of care by enacting an inflation-based update similar to what hospitals receive under the IPPS and the Outpatient Prospective Payment System (OPPS)***.

MDC 05 (Diseases and Disorders of the Circulatory System): WiSE® CRT System
The WiSE® cardiac resynchronization therapy (CRT) system is an implantable cardiac pacing system that delivers left ventricular endocardial pacing (LVEP) specifically for CRT with the use of wires or leads going into the heart.

CMS received a request to re-examine MS-DRG assignments based on clinical coherence between procedures involving WiSE® and intracardiac or leadless pacemakers for FY 2027. In response, CMS is proposing the following changes to the assignments to categorize cases based on whether they are performed via a percutaneous or open approach.

Specifically, CMS proposes the following changes for the WiSE® CRT System:

- CMS proposes to reassign ICD-10 procedure code X2HN37B (*Insertion of endocardiac pacing electrode into left ventricle, percutaneous approach, new technology group 11*) from MS-DRG 264 (*Other Circulatory System O.R. Procedures*) to MS-DRG 228 (*Other Cardiothoracic Procedures with MCC*) and MS-DRG 229 (*Other Cardiothoracic Procedures without MCC*).
- CMS proposes to delete the procedure code combinations describing the procedure from the assignment logic for the following MS-DRGs:
    - MS-DRG 242 (*Permanent Cardiac Pacemaker Implant with MCC*)
    - MS-DRG 243 (*Permanent Cardiac Pacemaker Implant with CC*)
    - MS-DRG 244 (*Permanent Cardiac Pacemaker Implant without MCC*)
- CMS proposes that standalone reporting of ICD-10 procedure code XHH80HB (*Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11*) will be assigned to new MS-DRG 210 (*Cardiac Pacemaker Revision or Device Replacement with MCC*) and MS-DRG 211 (*Cardiac Pacemaker Revision or Device Replacement without MCC*).

In proposing an assignment logic that directs percutaneous approach cases to "Other Cardiothoracic Procedures" MS-DRGs and directs the open approach version of the procedure into the new

"Cardiac Pacemaker Revision or Device Replacement" MS-DRGs, we believe CMS has developed a reasonable approach for ensuring that MS-DRGs maintain clinical coherence and are valued to reflect the resource intensity of the cases when delivered in the inpatient setting. ***The Society strongly supports the proposed changes and urges CMS to finalize the reassignment of X2HN37B to MS-DRGs 228 and 229, and delete the procedure code combination from the GROUPER logic for FY 2027.***

Proposed FY 2027 Applications for New Technology Add-On Payments (Alternative Pathways) for Breakthrough Devices

CMS received a New Technology Add-On Payment (NTAP) application from Cara Medical for its CARA System which is a CT angiography (CTA)-based AI/ML platform comprising two integrated components: the CARA Metis Simulator, which generates a patient-specific three-dimensional map of the cardiac conduction system from pre-procedural CT angiography for pre-procedural planning, and the CARA Atlas Navigator, which overlays that personalized map onto live fluoroscopic images for intra-procedural guidance. CMS proposes to approve the NTAP in the amount of $10,205 for FY 2027, contingent upon the technology receiving FDA marketing authorization, and seeks input on whether the NTAP would be appropriate in instances where only one component of the CARA System is utilized.

The FDA granted the CARA System Breakthrough Device Designation (Q250281) on February 27, 2025, and issued 510(k) clearance (K252500) on February 20, 2026. The cleared indication encompasses both percutaneous and surgical procedures in regions adjacent to the cardiac conduction system, including transcatheter aortic valve replacement (TAVR) and other structural heart interventions, as well as procedures intended to deliver therapy to the conduction system, including conduction system pacing (CSP).

While we understand that CMS is seeking clarification on the components and process for use of the CARA Atlas Navigator and the CARA Metis Simulator, the Breakthrough Device Designation encompasses the system as a whole. From a clinical perspective, the three use-scenarios (interventional, surgical, planning-only) all serve a single clinical purpose of equitable importance: making the conduction system visible to the operator. Artificially distinguishing between these scenarios for payment purposes does not reflect the clinical reality of how the technology is deployed or the patient benefit it confers.

The CARA System provides personalized, patient-specific anatomic visualization of the cardiac conduction system different from existing technologies and represents a substantial clinical improvement over existing treatments that fulfills a previously unmet need in patient care. ***The Society supports approval of the CARA System application under the alternative NTAP pathway. If CMS determines that components of the CARA System are not eligible for the alternative NTAP pathway, we strongly urge CMS to consider approving the system and its components under the traditional NTAP pathway.***

Proposed FY 2027 Status of Technologies Approved for FY 2026 New Technology Add-On Payments

For FY 2027, CMS is proposing to extend NTAP for 41technologies that have not yet reached their maximum eligibility period. This includes the PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter and the WiSE® CRT System. ***The Society supports continued NTAP eligibility for these technologies and urges CMS to finalize the proposal for FY 2027.***

Proposed Alternative Pathway Repeal for NTAP and Outpatient Prospective Payment System (OPPS) Device Pass-through

CMS proposes to repeal the alternative pathway for NTAP, citing concerns that its limited evaluation process does not sufficiently assess the substantial clinical improvement criterion. Under the current alternative pathway, technologies that have received the FDA Breakthrough Device Designation, Qualified Infectious Disease Product (QIDP) designation, or approval under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) are automatically deemed to satisfy both the newness and substantial clinical improvement criteria. As a result, the technologies are only required to meet the cost criterion to qualify for an NTAP. If the proposal is finalized, all new services and technologies would be required to meet the full eligibility criteria (newness, cost, and substantial clinical improvement) for FY 2028 and subsequent years.

Similarly, CMS proposes to repeal the alternative device pass-through pathway under the Outpatient Prospective Payment System (OPPS). Under this proposal, all applications received for OPPS device pass-through payment status on or after October 1, 2026 would be required to demonstrate that the technology meets the same eligibility requirements, including that the technology offers a substantial clinical improvement. ***The Society opposes the proposals and urges CMS to preserve the alternative NTAP and OPPS Device Pass-through pathways, which have been instrumental in expanding patient access to breakthrough technologies.***

In the proposed rule, CMS asserts that the pathways have resulted in inappropriate approvals, excess spending, and adverse patient outcomes, yet provides no evidence to substantiate these claims. We are concerned that the proposed implementation timelines are insufficient to allow for meaningful stakeholder engagement or assessment of the policy's impact. ***At a minimum, HRS urges CMS to maintain the current processes while initiating a collaborative, evidence-based review of the impact that removal of the pathways will have on patient access to new technologies. As part of that, we urge CMS to release additional data on the alleged unintended consequences of the current policy so that stakeholders can work constructively with CMS to address any legitimate program integrity concerns, while ensuring patients have access to these lifesaving technologies.***

Proposal to Adopt a Unique Device Identifiers for Implantable Medical Devices Measure in Medicare Promoting Interoperability Program

CMS proposes a new measure for the Medicare Promoting Interoperability Program that would require eligible hospitals and critical access hospitals to electronically capture and store the complete Unique Device Identifier (UDI) for each implantable medical device within the patient's electronic health record (EHR). The measure would fall under the Public Health and Clinical Data Exchange objective and take effect beginning with the CY 2027 EHR reporting period. Under the proposal, hospitals would attest to using certified EHR technology (CEHRT) to capture and store the UDI for each implantable medical device within the patient's EHR as a discrete data element. CMS is also soliciting feedback on whether the measure should eventually shift to a performance-based framework.

HRS generally supports collecting UDIs for implantable devices as an important step toward improving patient safety. Reliable capture of UDI data is foundational for effective device tracking, patient safety, and research. We believe electronic UDI capture would enable more accurate reporting of adverse events, facilitate post-market surveillance, and improve recall

management. Without it, electrophysiologists and other device-based specialties remain dependent on incomplete sources such as manufacturer reporting and the FDA MAUDE (Manufacturer and User Facility Device Experience) system, which limits the ability to detect and respond to device-related recalls and updates. However, additional information is needed regarding the administrative burden this new requirement would place on both physicians and hospitals before the measure is finalized. ***We urge CMS to consider how to best maximize automation of UDI capture electronically to ensure that clinical care teams do not need to rely on manual documentation, which increases the risk of errors from data entry. Finally, if CMS moves forward with this attestation-based measure, we ask that CMS allow sufficient time for hospitals to implement the measure before considering or proposing a shift to a performance-based metric.***

In summary, the Society respectfully urges CMS to adopt the following actions:

- **Finalize the MS-DRG changes for FY 2027 to which cardiac electrophysiology inpatient cases are assigned.**
- **Work with Congress to modify the MPFS annual payment update to reflect the increasing costs of care by enacting an inflation-based update similar to what hospitals receive under the IPPS and the OPPS.**
- **Finalize the reassignment of X2HN37B to MS-DRGs 228 and 229 for the WiSE® CRT System, and delete the procedure code combination from the GROUPER logic for FY 2027.**
- **Approve the CARA System application under the alternative NTAP pathway as proposed.**
- **Continue NTAP eligibility for FY 2027 for the PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter and the WiSE® CRT System.**
- **Preserve the alternative NTAP and OPPS Device Pass-through pathways, initiate a collaborative, evidence-based assessment of the impact on patient access to new technologies, and provide data on the alleged unintended consequences of the current policy before changing it.**
- **Consider how to best maximize electronic UDI capture and EHR storage without increasing administrative burden for hospitals or physicians.**

Conclusion

HRS appreciates the opportunity to provide comments on the IPPS proposals for FY 2027. If you have any questions, please contact Lisa Miller, Senior Director of Reimbursement and Health Policy at LMiller@hrsonline.org or (202) 464-3413.

Sincerely,

Sana M. Al-Khatib, MD, MHS, FHRS
President
Heart Rhythm Society