



September 9, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Submitted electronically via <https://www.regulations.gov>

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule [CMS-1809-P]

Dear Administrator Brooks-LaSure:

The Heart Rhythm Society (HRS) is the world 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 (EP) 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.

Proposed Additions to the List of ASC Covered Surgical Procedures

We are writing this letter to kindly request strong consideration for including the cardiac catheter ablation codes in the Centers for Medicare & Medicaid Services (CMS) Ambulatory Surgical Center (ASC) payment system final rule for calendar year (CY) 2025. **It is our position that cardiac catheter ablations can be safely performed on an ambulatory basis in appropriately selected Medicare patients as adjudicated by physician judgment (with case selection determined by patient clinical and social considerations, physician experience, and facility support).**

To better reflect concerns from our EP physicians regarding patient access, in 2023 HRS and ACC (American College of Cardiology) established a joint workgroup to develop:

- A) A survey to assess the current clinical landscape of ablation in the ASC setting,
- B) A strategy that aligns with patient and physician needs; and
- C) A document to inform interested stakeholders in healthcare delivery.



The results of the aforementioned survey were published in the medical journal *Heart Rhythm*. The survey¹ revealed the following:

- 1) Cardiac catheter ablation procedures have increasingly moved toward same-day discharge.
- 2) Cardiac catheter ablations are increasingly being performed in the ASC setting to address patient access issues.
- 3) A majority of EP physicians support cardiac catheter ablation procedures in ASC settings.

As you might recall in May 2024, HRS and the ACC jointly sent a letter to the CMS Hospital and Ambulatory Policy Group (HAPG) characterizing our position on cardiac catheter ablation services performed in the ASC setting. In this letter we strongly encouraged CMS to include the aforementioned services in the proposed rule for public comment.

As CMS acknowledged in previous final rules, ongoing review is necessary to determine if changes in technology or medical practice affect the clinical appropriateness of performing cardiac ablation procedures in the ASC setting. On August 6, 2024, HRS and ACC convened a virtual meeting with the HAPG. The purpose of this meeting was to discuss and further elaborate our strong support to add cardiac catheter ablation services to the ASC Covered Procedure List (CPL). Current regulatory criteria (42 CFR 416.166) in order for a service to be added to the ASC-CPL, state that “the surgical procedure must be separately paid under the OPSS, must not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.”

To address these requirements, we shared compelling, peer-reviewed, real-world evidence (including outcomes from the Hospitals Without Walls Program authorized by CMS during the pandemic era) and CMS CY 2022 claims data to support our request. Our analysis of CMS CY 2022 hospital outpatient claims data suggested that cardiac catheter ablation procedures, often performed with same-day discharge, had lower complication rates (along with lower admission rates and ED visits) than cardiovascular procedures that were already covered in the ASC CPL (i.e., pacemaker/ICD implantation procedures, elective percutaneous coronary intervention (PCI) procedures and peripheral vascular interventions). These findings are summarized in the Table below.

¹ Liu CF, Hurwitz JL, Shanker AJ, et al. Heart Rhythm Society's survey assessing same-day discharge after electrophysiology procedures and implementation in ambulatory surgical centers. *Heart Rhythm*. April 02, 2024, <https://doi.org/10.1016/j.hrthm.2024.03.1812>

Table: Analysis of CMS OPSS Claims Data for CY 2022

Analysis of CMS 2022 OPSS Claims Data Show No Significant Safety Risk to Patients

Abbreviations:
 PCI = percutaneous coronary intervention
 DES = drug eluting stent
 PTCA = percutaneous transluminal coronary angioplasty
 PM = pacemaker
 ICD = implantable cardioverter defibrillator
 SVT = supraventricular tachycardia
 VT = ventricular tachycardia
 AF = atrial fibrillation.

Procedure (Code)	Total Procedures (n)	Resulted in Inpatient Admission within 1 Day	Resulted in Inpatient Admission within 30 Days	Emergency Room Visit within 1 Day
PCI-DES, single vessel (C9600)	97,817	2,150 (2.2%)	8,905 (9.1%)	1,419 (1.5%)
PTCA, single vessel (92920)	9,384	294 (3.1%)	1,066 (11.4%)	189 (2.0%)
PM insertion, dual leads (33208)	42,475	824 (1.9%)	3,052 (7.2%)	936 (2.2%)
PM gen change, dual (33228)	29,429	90 (0.3%)	1,328 (4.5%)	119 (0.4%)
ICD implant (33249)	20,117	255 (1.3%)	1,580 (7.9%)	65 (0.3%)
AV node ablation (93650)	8,425	64 (0.8%)	831 (9.9%)	21 (0.2%)
SVT ablation (93653)	22,489	208 (0.9%)	1,064 (4.7%)	46 (0.2%)
VT ablation (93654)	5,792	74 (1.3%)	369 (6.4%)	6 (0.1%)
Add-on SVT/VT ablation (93655)	34,011	380 (1.1%)	2,331 (6.9%)	65 (0.2%)
AF ablation (93656)	62,149	784 (1.3%)	4,252 (6.8%)	82 (0.2%)
Add-on AF ablation (93657)	24,670	322 (1.3%)	1,968 (8.0%)	-

Moreover, survey data was presented indicating an emerging shift in practice trends from the outpatient hospital facility to the ASC setting for all procedures, including cardiovascular procedures such as cardiac ablations. Finally, we also discussed how cardiac catheter ablation procedures were already covered in the ASC setting by many private insurers.

It is important to note that the data showing the strong safety outcomes reflect the appropriate selection of patients for the ASC setting. The ASC setting will not be appropriate for all catheter ablation procedures, and HRS will be publishing guidelines for safe selection of patients for same-day discharge and outpatient settings. However, all told, the real world clinical and survey data presented unequivocally supported the notion that cardiac ablation services can be safely performed in appropriately selected patients in the ASC setting.

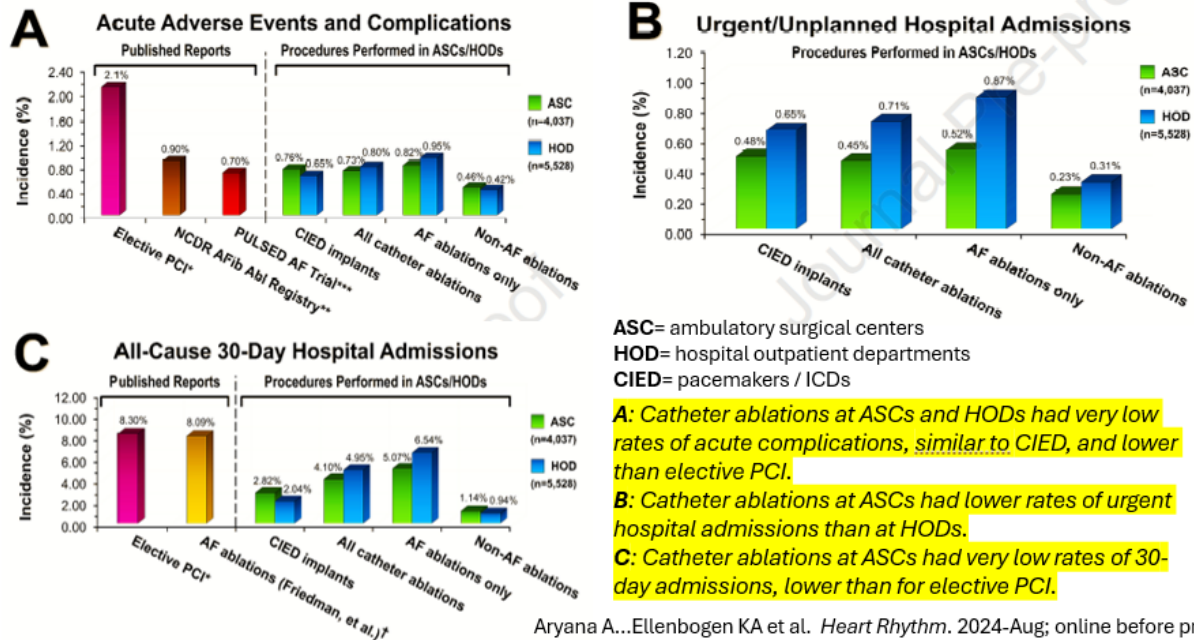
We would like to point out that CMS had recently authorized cardiac catheter ablations (along with other cardiac EP procedures) to be performed for its beneficiaries in ASCs during the COVID-19 pandemic as part of the Hospitals Without Walls Program. HRS recently reported the outcomes from this program: a large, multicenter safety and feasibility cohort² of more than 4,000 cardiac electrophysiology procedures performed across six ASCs. Findings from the study demonstrated that catheter ablations performed in ASCs and hospital outpatient departments had similarly low rates of acute complications, comparable to pacemakers/ICD implants and lower than elective PCI procedures (both cardiac procedures already covered in the ASC CPL). Catheter

² Aryana A, Thihalolipavan S, Willcox ME, et al. Safety and Feasibility of Cardiac Electrophysiology Procedures In Ambulatory Surgery Centers. *Heart Rhythm* (2024), <https://doi.org/10.1016/j.hrthm.2024.07.123>



ablation procedures performed in the ASC setting additionally demonstrated trends toward lower rates of urgent hospital admissions than at hospital outpatient departments, and very low rates of 30-day admissions, lower than for elective PCI. These findings are summarized in the Figure below.

Hospitals Without Walls Program (CMS, COVID-19 PHE 2020-23)



In previous consecutive years, other stakeholders involved in healthcare delivery have requested that the cardiac ablation codes be included in the ASC CPL. CMS has responded that cardiac catheter ablation services are “inherently non-surgical.” We strongly disagree with this statement and respectfully request CMS to better clarify this position. We also request clarification on why some, but not all, codes submitted through the MEARIS™ portal for ASC CPL Pre-Proposed Rule Recommendation Request were not mentioned in the CY 2025 proposed rule.

Based on available global real world evidence, safety data, CMS OPPS claims data (including the Hospitals Without Walls Program) and practice survey results (reflecting real world EP practice), we would strongly urge CMS to add cardiac catheter ablation services when finalizing the ASC CPL for CY 2025.

HRS appreciates the opportunity to offer comments on the proposed rule for the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems for CY 2025. If you have any questions or would like to discuss our comments, please contact Lisa Miller, 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