August 28, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–3421–NC
P.O. Box 8010
Baltimore, MD 21244-1810

Submitted electronically via www.regulations.gov

RE: Medicare Program; Transitional Coverage for Emerging Technologies (CMS-3421-NC)

Dear Ms. Brooks-LaSure:

On behalf of the Heart Rhythm Society (HRS), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed pathway for transitional coverage for emerging technologies (TCET). 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 8200 members in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health professionals. Electrophysiology is a distinct specialty of cardiology, with eligibility for board certification in both clinical cardiology and clinical cardiac electrophysiology through the American Board of Internal Medicine. In the U.S., HRS represents 3600 board certified electrophysiologists.

The specialty of electrophysiology is dedicated to saving and enhancing the life of its patients through advances in medical technology. **Since our members are highly dependent on medical technology and other rapid innovations, we support the creation of an alternative, expedited pathway to coverage and payment for emerging devices and diagnostics in order to improve access to new technology for Medicare beneficiaries**. Currently, once a device obtains FDA approval, there is a delay to securing Medicare coverage for use of that device. This process is often lengthy and uncoordinated, and routinely results in coverage delays and inconsistent coverage determinations, which in the end, can delay a patient's access to life-saving therapies. An expedited coverage pathways would enhance patients' access to critical devices that have been designated by the FDA as qualifying for the breakthrough devices program because they provide more effective treatment or diagnosis of a life-threatening disease or condition.

At the same time, we are concerned that the proposed TCET process is not as expeditious as the previously proposed Medicare Coverage of Innovative Technology (MCIT) pathway. The MCIT pathway would have granted devices with breakthrough designation *immediate* transitional national coverage upon marketing (or a date specified by the manufacturer) for four years. Coverage under the proposed TCET pathway, on the other hand, would not be immediate and would instead build off of the Medicare national coverage determination (NCD) process and Coverage with Evidence Development (CED), which could take six months or more. **HRS urges CMS to consider ways**

to make "day 1" coverage and payment possible, while still relying on aspects of the CED NCD process to accommodate evidence generation and "fit for purpose" studies.
We are also concerned about CMS' proposal to limit TCET nominations to five technologies per year and the lack of specific criteria regarding how CMS will select candidates eligible for the pathway. **CMS should not impose arbitrary limits on the number of technologies eligible for approval under this pathway and should instead base these decisions on a fully transparent and careful evaluation of the clinical evidence and the needs of patient populations**.

Finally, HRS supports expanding expedited coverage pathways beyond devices to include diagnostics and drugs. The EP field has rapidly evolved in terms of the new technologies and therapies used to both diagnose and treat a wide range of arrhythmias. Adopting this pathway on a broader scale will support more accurate identification and appropriate treatment of patients with heart rhythm disorders.

Again, HRS generally supports efforts to provide timely and reliable Medicare coverage for breakthrough medical devices and technologies. We thank CMS for engaging stakeholders on this topic. Should you have any questions, please contact Lisa Miller, Senior Director of Health Policy and Reimbursement at LMiller@hrsonline.org or (202) 464-4313.

Sincerely,

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