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November 2, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—December 7, 2022 [CMS-3431-N]

Dear Administrator Brooks-LaSure,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Virtual Meeting of the Medicare Evidence Development and Coverage and Advisory Committee (MEDCAC) which will examine the general requirements for clinical studies submitted for CMS coverage requiring coverage with evidence development (CED). Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,600 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

During the December 7 meeting, the MEDCAC will evaluate the CED criteria to assure that CED studies are evaluated with consistent, feasible, transparent and methodologically rigorous criteria and advise CMS on whether the criteria are appropriate to ensure that CED-approved studies will produce reliable evidence to determine whether a particular item or service is reasonable and necessary.

STS supports the development and use of data collection systems to ensure that patients, providers, and CMS can make decisions based on the best available clinical evidence. To that end, we strongly support CMS' utilization of CED. We believe that CED ensures that beneficiaries have appropriate access to new medical technologies and services at an earlier stage in their development. In addition, CED that leverages the real-world-evidence of clinical data registries is a powerful tool for informed decision making.

We believe that the health care community, and the physician community in particular, has the ability and the responsibility to play an active role in the CED process. However, similar to many other stakeholders, we support collaboration, efficiency, and reduced burden when implementing the CED pathway. Since the beginning of CED in 2004, CMS's policy has allowed more rapid access to new interventions for Medicare beneficiaries, improved post-market evidence development, provided important new evidence for health care decisions, and facilitated clearer understanding of the risks and benefits of cardiovascular therapies for patients, providers, and payers. During the past decade, the STS/ACC TVT Registry™ and Coordinated Registry Network supported 23 regulatory decisions and

ensured evidence-based evaluation of TVT technology. This method of evidence generation creates value for manufacturers and the broader device ecosystem with significant benefits to the public health.

STS believes that data collection and the pursuit of quality improvement encourages collaboration among different stakeholders including professional societies, government agencies, industry, and patient groups. Different government agencies often have dissimilar evidentiary needs, forcing stakeholders to generate varied data for different stakeholders to understand how new technologies work in patients. This can be accomplished by supporting the integration of clinical and administrative data which allows for near real time clinical analyses and feedback to stakeholders. This includes for the purpose of quality improvement in value-based care. Protocols should be designed to enhance the ability for partnerships among industry members to better align development and data collection efforts and to meet the needs of regulators, payers, and patients.

STS' experience with the STS/ACC TVT Registry™ demonstrates that this model is an effective platform to support collaboration and meet the needs of varied stakeholders. The STS/ACC TVT Registry™ relies on the integration of clinical and administrative data (i.e., clinical data can be linked to CMS MEDPAR information) to obtain longitudinal outcomes data. The Registry tracks relevant outcomes, which allows stakeholders to use the information to enhance evidence-based shared decision-making with patients and caregivers.

It is important to start the data collection early in the coverage process to ensure sufficient time to identify and capture the appropriate data elements and engage relevant stakeholders. During the TAVR effort, STS and ACC initiated conversations with CMS, FDA, and other relevant stakeholders early to ensure upfront agreement on the components and structure of the STS/ACC TVT Registry™. Lessons learned from STS/ACC's experience developing the STS/ACC TVT Registry™ suggest that CED review policy decisions can be successful if federal agencies facilitate early discussions among relevant stakeholders to ensure appropriate application, design, and implementation of CED.

Data collection should evolve in order to respond to the changing evidentiary and technology landscape, which may introduce new or different indications, outcomes, and subpopulations. Data collection should be used to identify anomalies, target the causes of adverse events, or identify the reason for changes in outcomes. Registries provide a pragmatic way to develop answers to questions and registry data collection crosses agency boundaries providing a tangible asset to address a number of regulatory pathways.

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Senior Manager of Regulatory Affairs, at mpeltzman@sts.org or 202-787-1221 should you need additional information or clarification.

Sincerely,

John H. Calhoon, MD
President