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AMERICAN  
COLLEGE of  
CARDIOLOGY



SCAI  
Society for Cardiovascular  
Angiography & Interventions



May 30, 2019

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Dear Administrator Verma,

The Society of Thoracic Surgeons (STS), the American College of Cardiology (ACC), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography & Interventions (SCAI) are writing to reiterate our comments on the proposed national coverage decision (NCD) for transcatheter aortic valve replacement (TAVR) and affirm our commitment to providing patients access to the best and safest treatment options for aortic stenosis. Our joint comment letter on the proposed NCD has been included here for reference. However, we are writing today to address specific concerns that have recently been raised outside of the process of notice and comment on the proposed NCD.

In the proposed NCD, the Centers for Medicare & Medicaid Services (CMS) changed the existing requirements for TAVR patients to have pre-procedure consultation with two cardiac surgeons to a requirement for pre-procedure consultation with one cardiac surgeon. The societies support this change. The existing requirement was a carryover of pivotal clinical trials but is now commonly an obstacle to care as the technology has dispersed. The societies further affirm that patient evaluation is optimally performed jointly in a multidisciplinary valve clinic. Patient preferences with regard to surgical aortic valve replacement (SAVR) or minimally-invasive TAVR and outcomes that matter most to them must be considered. The multidisciplinary valve clinic is a preferred venue for shared decision-making as opposed to separate “face to face” consultations with a cardiologist and a surgeon. We recommend that CMS provide clarification in coverage condition 2 by specifically noting that the pre-procedural consultation be performed by a surgeon and interventional cardiologist who are part of the heart team.

The value of the heart team has been proven to improve quality across the spectrum of care for heart patients. The team-based approach to TAVR is critical to maintaining high quality programs and preventing patient harm.

At the July 2018 Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting the societies presented information on racial disparities in access to TAVR. Presenters noted that, according to the most recent census, 15 percent of Americans are African

Americans and 17 percent are Hispanic. However, only 6.5 percent of Americans aged 65 or older were African American and 7.5 percent were Hispanic. Recall that, to date, TAVR has only been performed in high and intermediate risk populations, meaning that the patients who have historically received TAVRs are older and frailer than the rest of the population. That may help to explain why data from the STS/ACC TVT Registry suggest that only four percent of TAVRs were performed in African American patients and 4.3 percent are performed in Hispanic patients.

As a point of comparison, reports from the STS National Database, which captures data on >95% of adult cardiac surgical procedures performed across the country, demonstrate that 5.7 percent of SAVR procedures were performed in African American patients. The demographic rates are comparable despite nearly twice as many centers performing SAVR versus TAVR. These numbers do not suggest disproportionately inadequate access to TAVR care for African American and Hispanic populations. Racial disparities are seen across the health care system, such as in access to and outcomes of cancer care.<sup>1,2</sup>

Barriers to medical care in the United States are complex, and access to TAVR is no different. Socioeconomic, cultural, and transit obstacles can hinder patient access to health care anywhere in the country. To that end, education of providers throughout the healthcare system must increase significantly, in a focused and structured manner, so that candidates for TAVR therapy are correctly identified and referred for specialized valvular disease care. We must commit to better educating patients, primary care physicians, and other care providers in underserved communities to better diagnose aortic valve disease and help patients obtain access to the care they need. There is no evidence that additional TAVR centers or further changes to pre-procedure consultation standards will address disparities of care in the management of aortic stenosis.

Thank you for considering this supplementary comment as the Agency works toward a finalized TAVR NCD in the coming weeks. Please contact Courtney Yohe at [cyohe@sts.org](mailto:cyohe@sts.org) or 202-787-1222 with questions or for additional information.

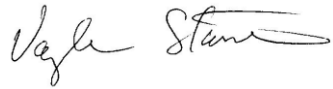
Sincerely,

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<sup>1</sup> [Esnaola, N. Surg Oncol Clin N Am. 2012 Jul; 21\(3\): 417–viii.](#)

<sup>2</sup> [Yanez, B. J Lat Psychol. 2016 May; 4\(2\): 114–129.](#)

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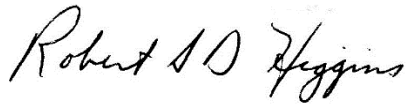
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