Congress of the United States
Washington, DC 20515

May 14, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

The Centers for Medicare and Medicaid Services (CMS) recently released its draft document containing guidelines for the reconsideration of the 2012 National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR), a life-saving treatment for aortic stenosis. This is deadly and debilitating condition affects more than two million people in the United States. We recognize these guidelines are an important step in modernizing the outdated policy and ask that you consider the impact your decision has on access and treatment disparities in minority and underserved patient populations with valvular heart disease.

Severe aortic stenosis is a deadly disease in which aortic valve replacement is the only effective treatment. While survival rates without treatment are low at 50 percent at 2 years after symptom onset, many with the disease are never diagnosed or treated, and this is especially true among minority groups.[1] Disparities to TAVR access may result from multiple complex factors including socioeconomic disparities, inherent biases in healthcare provision, fewer referrals to specialists, poor cultural competency and language barriers.[2] A recent study in the New England Journal of Medicine has shown that TAVR is superior to surgical valve replacement for high-risk patients, and the same for low-risk patients. [3] This new data could change the paradigm of treatment for individuals with aortic stenosis.

Addressing racial disparities in the NCD is an important first step in improving the disparities in access to this treatment. Currently, 94 percent of patients receiving TAVR are white, and according to the Alliance for Aging Research, 78 percent of TAVR patients served by hospitals are in higher

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[1] *Chronic Disease and Medical Innovation in an Aging Nation, The Silver Book: Valve Diseases.* P.6, https://www.silverbook.org/wp-content/uploads/2018/02/Silver-Book-Valve-Disease-VOLUME-Final-2.pdf

[2] Bob-Manuel T, Sharma A, Nanda A, Ardeshna D, Skelton WP 4th, Khouzam RN. A review of racial disparities in transcatheter aortic valve replacement (TAVR): accessibility, referrals and implantation. Ann Transl Med. 2018;6(1):10. doi:10.21037/atm.2017.10.17

[3] Mack, Michael et al, *Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients*; New England Journal of Medicine; 10.1056/NEJMoa1814052; https://www.nejm.org/doi/full/10.1056/NEJMoa1814052

income zip codes.[4,5] One way to improve access to TAVR for these populations is to allow an interventional cardiologist or a surgeon with knowledge of all treatment options to evaluate the patient. Allowing additional providers to evaluate patients for TAVR can help a more diverse population of patients have access to this effective treatment option. In the proposed draft, limiting the evaluation exclusively to a cardiac surgeon is a hurdle that may unintentionally further prevent minority and underserved patients from receiving the most appropriate treatment.

In conclusion, we commend CMS for initiating the reconsideration of the TAVR NCD and support the inclusion of many of the elements in the current draft. However, we ask CMS to consider the impact of the proposal on minority populations and work to ensure access to TAVR for all Medicare patients, regardless of race, ethnicity, socioeconomic status, or zip code.

Sincerely,

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[4] Grover, F, S Vemulapalli, J Carroll, F Edwards, M Mack, et al. 2017. 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. JACC 69(10)

[5] Analysis performed using HCUP Net Database for 2015 Hospital Discharges. https://hcupnet.ahrq.gov/#setup.

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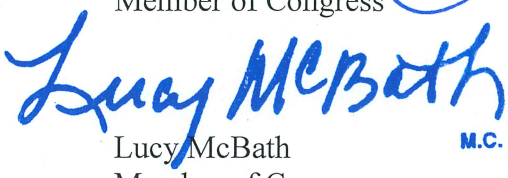

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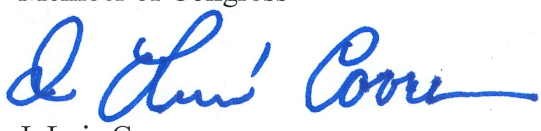

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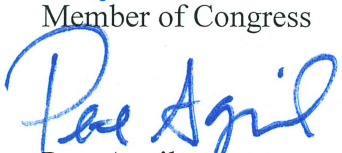

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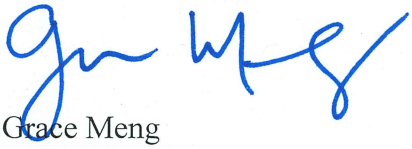

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