

April 25, 2019

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244

Dear Administrator Verma:

The undersigned organizations are writing with our response to the Centers for Medicare & Medicaid Services' (CMS) updated proposed decision on Medicare's National Coverage Decision (NCD) for transcatheter aortic valve replacement (TAVR) (CAG-00430R). Collectively, we represent heart valve disease patients, family caregivers, aging organizations advocates for minority and women's health, and cardiologists.

We applaud the agency's movement toward making this policy less onerous for patient access, including the change in the two-surgeon evaluation requirement and reduction in TAVR program establishment requirements. We appreciate the agency is open to public reporting of health outcomes data and that CMS recognizes continued barriers to access for minority populations need to be addressed. We also appreciate that CMS will not require shared decision-making in the absence of an evidence-based decision aid that meets standards consistent with the *National Quality Partners Playbook™ on Shared Decision-Making*, while recognizing the importance of shared decision-making and urging its development.

We are extremely concerned that the proposed decision continues to prioritize patient access based on hospitals' procedural volume ahead of equal access and quality care for all Medicare beneficiaries. The extensive data collected through the Transcatheter Valve Therapy (TVT) Registry and numerous randomized controlled trials have demonstrated that TAVR is a reasonable and necessary alternative to open-heart surgery. These data prove that TAVR improves health outcomes for Medicare beneficiaries with symptomatic severe aortic stenosis for FDA-approved indications. These data also affirm that a Coverage with Evidence Development (CED) is no longer needed. Therefore, ***we request CMS cover TAVR under a NCD for FDA-approved uses, removing the CED-based restrictions proposed.***

We recognize that some may view TAVR as a disruptive technology to the current practice of cardiovascular medicine, but it has been demonstrated beyond doubt that TAVR is an important step forward, as shown by extensive reported data. Similarly, when large-scale change occurs, we recognize the benefits of having the power of CED applied when data are unavailable, but an enormous body of clinical data already exists in the case of TAVR.

The rationale for our recommendations (and the request to transition from an NCD with CED to an NCD with coverage to label) can be summarized as follows:

- The available evidence, which continues to grow, is more than enough to conclude that TAVR improves health outcomes for Medicare beneficiaries with severe symptomatic aortic stenosis for FDA-approved indications;
- Public reporting of hospital-based health outcomes data should be used in lieu of annual procedural volume requirements. Such volume requirements do not ensure quality and impede

access for racial and ethnic minorities, women, and rural beneficiary populations and could continue to create service barriers for patients treated by the smaller hospitals that serve them;

- Health outcomes data for individual TAVR programs collected by the TVT Registry are kept private from the public, which impedes quality improvement—there is no defensible rationale for keeping that hospital-specific information private;
- If FDA approval expands TAVR indications to patients at low-risk for surgery, and the CED and its program maintenance requirements remain, waiting lists at larger hospitals will lengthen and patients may die due to delays;
- The continuation of the CED requirement is contrary to the Administration’s “patients over paperwork” initiative and places unnecessary regulatory burdens and costs on providers that do not improve care for patients.

Patients are stuck in the midst of a professional sea change in heart valve disease treatment involving the specialist clinician, as well as between major medical centers and smaller, community-based/ rural hospitals. ***We appeal to CMS to amend its TAVR coverage decision to one that will be of the most benefit to all older adults, all racial and ethnic minorities, women, and all rural beneficiaries Medicare is charged to serve.***

### **Background: Seven Years of Extensive Evidence Development**

Efforts to institute a NCD (with a CED requirement) for TAVR was initiated in September 2011, after the presidents of the American College of Cardiology (ACC) and Society for Thoracic Surgeons (STS) sent a joint request letter to CMS.<sup>1</sup> This request was sent in anticipation of the first U.S. Food and Drug Administration (FDA) approval of a TAVR device for the treatment of severe symptomatic aortic stenosis in older adults who needed an aortic valve replaced but were too ill or frail to survive open-chest surgery. The letter outlined what the preferred NCD would look like, including detailed operator and institution requirements. These included a call for the establishment of sophisticated “centers of excellence” and recommended that “access to TAVR should not be universal and immediate but should be implemented in a controlled and regulated fashion.... The complexities of the management of valvular heart disease will require the infrastructure available only in regional referral centers with acceptable patient volume in valvular heart disease as established by the ACC and STS.”<sup>2</sup>

Less than a year later, in May 2012, CMS issued a NCD for TAVR under CED (20.32)<sup>3</sup>, addressing the requests in the joint letter. The NCD with CED includes separate coverage requirements for those TAVR procedures provided according to FDA-approved indications and for those procedures provided outside of FDA-approved indications. For the former, the NCD includes conditions of coverage such as volume requirements for heart teams and hospitals, as well as mandatory participation in a prospective, national, audited registry. These conditions of coverage generally follow recommendations outlined in a 2012 joint consensus statement from the societies.<sup>4</sup> For procedures provided outside of FDA-approved indications, the NCD requires TAVR procedures to be performed in clinical studies that meet requirements set forth in the NCD and approved by CMS.

---

<sup>1</sup> <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id257.pdf>.

<sup>2</sup> Ibid.

<sup>3</sup> [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&NCAId=257&NcaName=Transcatheter+Aortic+Valve+Replacement+\(TAVR\)](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&NCAId=257&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)).

<sup>4</sup> <https://www.acc.org/latest-in-cardiology/journal-scans/2012/02/01/18/40/expert-consensus-document-on-transcatheter-aortic-valve-replacement>.

As part of their initial request to CMS, the STS and ACC proposed development of the TVT Registry, which would be similar to other national registries they were managing at the time. The TVT Registry became operational on December 1, 2011. The “TAVR Data Collection Form v2.1” form, available on the TVT Registry website<sup>5</sup>, is eight pages long and includes the following sections:

- Patient demographics;
- The episode of care;
- History and risk factors;
- Pre-procedure status;
- Clinical data (medications, diagnostic catheterization and echo findings, detailed procedure information, information on whether any medications were given during the procedure, and device information);
- Post-implant procedure information;
- Adverse events and whether any interventions occurred;
- Post-procedure labs and tests;
- Discharge data (including a separate section on medications);
- Extensive follow-up data at 30 days and one year; and
- Detailed information on whether stroke and/or aortic valve re-intervention occurred.

According to a presentation at the 2019 Cardiovascular Research Technologies (CRT) conference (one of the world’s leading interventional cardiology conferences), as of January 22, 2019 the TVT Registry has collected information on 195,954 TAVR and 10,797 TAVR ViV (valve in valve) procedures, for a total of 206,751 patient records since 2012.<sup>6</sup> The website also provides a list of 50 published manuscripts based on the registry.<sup>7</sup>

In addition to the national TVT registry, there have been 26 approved clinical studies of TAVR since 2012.<sup>8</sup> From these clinical studies’ identifier numbers, ClinicalTrials.gov has automatically indexed 50 published studies.

There is no question that the CMS Coverage and Analysis Group (CAG) has conducted both the initial TAVR NCD and the 2018-2019 reconsideration process in a thoughtful and rigorous manner. The TVT Registry and TAVR clinical studies to-date have provided valuable insight for device innovation, facility and provider procedure optimization, clinical care improvements, and—most importantly—improved health outcomes for Medicare beneficiaries. The CED process has also identified important research and treatment access gaps that have yet to be fully addressed.

The question is, what is the evidence threshold needed to end the TAVR CED? Because CED falls under the NCD statutory authority, there is no specific enforcement mechanism to ensure timely research reporting compliance, which results in an ad hoc process that leaves Medicare beneficiaries in a state of

---

<sup>5</sup> <https://www.ncdr.com/WebNCDR/tvt/publicpage/data-collection>

<sup>6</sup> <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjQ6Labw9DhAhXts1kKHcCAA5wQFjAAegQIABAC&url=http%3A%2F%2Fwww.crtonline.org%2FAssets%2F7c53164f-cb22-4d7c-ac5e-32e246594185%2F636871962554730000%2F58a58708-33f2-4ca8-9be6-84506c33818a-pdf&usg=AOvVaw3ghJRPj-ny4clvp97TJNdT>

<sup>7</sup> [https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/february2018ncdrpublishedmanuscriptsbyregistry.pdf?sfvrsn=30d1d99f\\_10](https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/february2018ncdrpublishedmanuscriptsbyregistry.pdf?sfvrsn=30d1d99f_10)

<sup>8</sup> <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html>.

uncertainty regarding their treatment. In an August 2011 article, “Improving the Quality and Efficiency of the Medicare Program Through Coverage Policy,” the authors state, “The current authority is sufficiently ambiguous to prevent CMS from fully developing and implementing coverage with evidence development consistently and systematically.”<sup>9</sup>

In its 2014 guidance on CED, within the section “Ending CED”, CMS states that the purpose of the studies is to “produce evidence that will lead to revisions in Medicare coverage policies,” and cites two examples of completed CED processes—NCDs for oncologic uses of FDG PET, and ventricular assist devices.<sup>10</sup> ***The implication here is that there would be a clear beginning and end to the CED process.*** The “Ending CED” section further states that “a CED cycle is considered completed when CMS completes a reconsideration of the CED coverage decision and removes the requirement for study participation as a condition of coverage.”<sup>11</sup> The original conditions for imposing a CED program on TAVR no longer exist, and under CMS’ own rules, the conditions for ending the TAVR CED have been met.

As advocates who believe that all patients should have access to the right treatment at the right time and that all patients should have a voice in their own treatment decisions, we urge CMS to end the CED process for TAVR and transition it to a NCD with coverage to FDA-approved label. As outlined below, an extensive amount of evidence has been developed over the last seven years to support ending the TAVR CED process, and CMS can confidently declare success.

**The available evidence is more than enough to conclude that TAVR improves health outcomes for Medicare beneficiaries with symptomatic severe aortic stenosis for FDA-approved indications**

When it was first approved by the FDA in 2011, TAVR was an important advancement for older adults who needed an aortic valve replaced but were too ill or frail to survive open-heart surgery.<sup>12</sup> Over the last seven years, the success of the TAVR technology has been demonstrated. Previous randomized

---

<sup>9</sup> <https://www.urban.org/sites/default/files/publication/27516/412392-Improving-the-Quality-and-Efficiency-of-the-Medicare-Program-Through-Coverage-Policy.PDF>.

<sup>10</sup> <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360>.

<sup>11</sup> Ibid.

<sup>12</sup> Leon, M, C Smith, M Mack, D Miller, J Moses, et al. 2010. Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery. *N Engl J Med* 363(17):1597-1607.

clinical trials of TAVR with both balloon-expandable valves<sup>13, 14, 15, 16, 17, 18</sup> and self-expanding valves<sup>19, 20, 21, 22</sup> showed that, in patients who were at intermediate or high-risk for death with surgery, TAVR was either superior or non-inferior in health outcomes to standard therapies, including SAVR. Post-market registry data have shown comparable results to the clinical data.<sup>23</sup> The FDA has expanded TAVR approval<sup>24</sup> to include a large percentage of patients with aortic valve disease, and clinical practice guidelines have followed.<sup>25</sup>

Two recent studies of low-risk patients published in the March 2019 issue of the *New England Journal of Medicine* also had promising results. One tested the self-expanding CoreValve, Evolut R, and Evolut PRO valves in a low-risk patient population, and found that the 24-month estimated incidence of death or disabling stroke was similar in the TAVR and surgical arms, meeting the definition of statistical noninferiority but not superiority.<sup>26</sup> The other study reported that treatment with the balloon-expandable Sapien 3 transcatheter heart valve was better than surgery for the prevention of death, stroke, and rehospitalization at 1 year, the study's primary endpoint.<sup>27</sup> These studies were mentioned in the CMS proposed decision, and are being actively reviewed by CAG.

---

<sup>13</sup> Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011; 364: 2187-98.

<sup>14</sup> Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016; 374: 1609-20.

<sup>15</sup> Kapadia SR, Leon MB, Makkar RR, et al. 5-Year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomized controlled trial. *Lancet* 2015; 385: 2485-91.

<sup>16</sup> Mack MJ, Leon MB, Smith CR, et al. 5-Year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomized controlled trial. *Lancet* 2015; 385: 2477-84.

<sup>17</sup> Webb JG, Doshi D, Mack MJ, et al. A randomized evaluation of the SAPIEN XT transcatheter heart valve system in patients with aortic stenosis who are not candidates for surgery. *JACC Cardiovasc Interv* 2015; 8: 1797-806.

<sup>18</sup> Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet* 2016; 387: 2218-25.

<sup>19</sup> Popma JJ, Adams DH, Reardon MJ, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol* 2014; 63: 1972-81.

<sup>20</sup> Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med* 2014; 370: 1790-8.

<sup>21</sup> Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate risk patients. *N Engl J Med* 2017; 376: 1321-31.

<sup>22</sup> Gleason TG, Reardon MJ, Popma JJ, et al. 5-Year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. *J Am Coll Cardiol* 2018; 72: 2687-96.

<sup>23</sup> 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. *J Am Coll Cardiol* 69(10):1215-30.

<sup>24</sup> Shuren, T. June 14, 2017. How Creative FDA Regulation Led to First-in-the-World Approval of a Cutting-Edge Heart Valve. FDA Voice. Available at <https://blogs.fda.gov/fdavoices/index.php/2017/06/how-creative-fda-regulation-led-to-first-in-the-world-approval-of-a-cutting-edge-heart-valve/>.

<sup>25</sup> Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2017; 70: 252-89.

<sup>26</sup> <https://www.nejm.org/doi/full/10.1056/NEJMoa1816885>.

<sup>27</sup> <https://www.nejm.org/doi/full/10.1056/NEJMoa1814052>

The TVT registry data indicate that patients who undergo TAVR have experienced significantly shorter hospital stays and lower incidence of some major complications throughout the study period. Between 2012 and 2017, registry data show that:

- Median length of stay in the hospital has decreased from six days to two days;
- In-hospital mortality has decreased from 5.7% to 1.7%;
- 30-day mortality has decreased from 7.5% to 2.8%; and
- One-year mortality has decreased from 26.4% to 14%.<sup>28</sup>

Newer generation TAVR devices have also improved quality of life measures for patients in both the short (one month) and long term (one year) compared to previous-generation devices and SAVR.<sup>29</sup>

According to the TVT registry data, the median age for TAVR patients ranged between 81 and 84 years between 2012 and 2017.<sup>30</sup> One concern about TAVR is the lack of long-term durability data. In an octogenarian population, the focus on durability may be less of a concern. Even so, a 2017 study of core laboratory echocardiographic data five years post-procedure demonstrated excellent durability.<sup>31</sup>

In summary, TAVR has emerged from the seven-year NCD under CED as an effective and less invasive solution in management of patients with severe symptomatic aortic stenosis, with excellent clinical outcomes. TAVR has several advantages over SAVR, including shorter hospital stay and faster recovery, which is particularly relevant to older adults. For many patients, survival benefit is not the primary goal of treatment. In a recent study of patients undergoing TAVR (mean 84 years of age), only 7% stated that improved survival was their reason for seeking treatment.<sup>32</sup> For most patients, maintaining independence (30%) or the ability to do a specific activity (48%) was the reason provided.<sup>33</sup>

Further, risk-benefit calculations as one ages and for those with life-threatening diseases can vary throughout the lifespan and healthspan. For example, a recent study of patients with severe aortic stenosis indicated that patients over 60 years old would be willing to tolerate a 13.2% increase in risk of death and a 20.1% increase in risk of disabling, non-fatal stroke in exchange for the benefits of TAVR (reduced invasiveness and increased post-procedure independence).<sup>34</sup> Current TAVR procedural outcome data are well within this range of this Medicare beneficiary population's tolerance levels.

---

<sup>28</sup><https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjQ6Labw9DhAhXts1kKHcCAA5wQFjAAegQIABAC&url=http%3A%2F%2Fwww.crtonline.org%2FAssets%2F7c53164f-cb22-4d7c-ac5e-32e246594185%2F636871962554730000%2F58a58708-33f2-4ca8-9be6-84506c33818a-pdf&usg=AOvVaw3ghJRPj-ny4clvp97TJNdT>

<sup>29</sup>[http://interventions.onlinejacc.org/content/early/2018/05/25/j.jcin.2018.02.032?\\_ga=2.24087741.623686554.1555319171-1037540999.1531938679](http://interventions.onlinejacc.org/content/early/2018/05/25/j.jcin.2018.02.032?_ga=2.24087741.623686554.1555319171-1037540999.1531938679)

<sup>30</sup><https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjQ6Labw9DhAhXts1kKHcCAA5wQFjAAegQIABAC&url=http%3A%2F%2Fwww.crtonline.org%2FAssets%2F7c53164f-cb22-4d7c-ac5e-32e246594185%2F636871962554730000%2F58a58708-33f2-4ca8-9be6-84506c33818a-pdf&usg=AOvVaw3ghJRPj-ny4clvp97TJNdT>

<sup>31</sup> Douglas PS, Leon MB, Mack MJ, et al. Longitudinal hemodynamics of transcatheter and surgical aortic valves in the PARTNER trial. *JAMA Cardiol* 2017;2:1197–206. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5710363/>

<sup>32</sup> Coylewright M, Palmer R, O'Neill ES, Robb JF, Fried TR. Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis. *Health Expect* 2016;19:1036–43.

<sup>33</sup> Ibid.

<sup>34</sup> Marsh K, Hawken N, Brookes E et al. Patient-centered benefit-risk analysis of transcatheter aortic valve replacement [version 1; peer review: awaiting peer review]. *F1000Research* 2019, 8:394 (<https://doi.org/10.12688/f1000research.18796.1>)

## **Public reporting of hospital-based health outcomes data should be used in lieu of annual procedural volume requirements, which do not ensure quality**

The biggest debate regarding this coverage decision is about whether CMS should continue to require a minimum number of annual surgical and interventional cardiac procedures for a hospital to maintain a TAVR program. When the original policy was established in 2012, the number of annual procedures a given hospital or heart center performed was used as a surrogate for the quality of its care.<sup>35</sup>

This requirement made sense when the technology was new because there was limited data, and there was a learning curve. Early studies showed that increased experience from higher volume facilities led to better outcomes in inoperable-risk and high-risk patients.<sup>36</sup> However today enhanced technology, widespread training<sup>37</sup>, and group learning effectively eliminate the learning curve and positively impact outcomes, independent of procedural volume. TAVR health outcomes are now found to be excellent in both high- and low-volume facilities.<sup>38</sup>

A recent review of more than 61,000 cases from the TVT Registry puts the volume-outcomes debate to rest. The review, published in the February 2019 issue of *Journal of the American College of Cardiology*, found that with earlier-generation TAVR devices, once the learning curve was surpassed, the volume-outcomes relationship disappeared. The review also found that, *with the use of current generation TAVR devices, there is no longer a detectable learning curve or demonstrable volume-outcomes relationship.*<sup>39</sup>

Unfortunately, despite the evidence, STS and ACC have suggested more than doubling the annual procedural volume requirements for hospitals to maintain their TAVR programs.<sup>40</sup> This inward-looking perspective is not only counterintuitive to what the data tell us, but the requirement would unnecessarily restrict patient access by causing some existing TAVR facilities to close and prevent new ones from opening. We are very concerned about this because studies have shown that patient proximity to a hospital impacts facility choice, even when reported health outcomes differ significantly.<sup>41</sup>

According to data from the Healthcare Cost and Utilization Project, greater than 90% of TAVR procedures in the United States are performed in urban, teaching hospitals, and 78% of patients served by these hospitals are in higher income zip codes.<sup>42</sup> Additionally, safety net hospitals—those public hospitals that are often providers of last resort—perform approximately 20% of TAVRs.<sup>43</sup>

There have been a few published studies that use TVT Registry data to support the volume-outcomes hypothesis, even as actual health outcomes from hundreds of thousands of procedures have accumulated in the registry. While CMS incorporated annual procedural volume requirements in the

---

<sup>35</sup> <https://www.tctmd.com/news/high-quality-tavr-does-minimum-volume-requirement-still-make-sense>.

<sup>36</sup> <https://www.sciencedirect.com/science/article/pii/S073510971737328X?via%3Dihub>

<sup>37</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5299191/>.

<sup>38</sup> <https://www.karger.com/Article/FullText/440694>

<sup>39</sup> <https://www.sciencedirect.com/science/article/pii/S0735109718393458?via%3Dihub>

<sup>40</sup> [http://www.onlinejacc.org/content/early/2018/06/20/j.jacc.2018.07.002?\\_ga=2.192222954.1972166338.1531938679-1037540999.1531938679](http://www.onlinejacc.org/content/early/2018/06/20/j.jacc.2018.07.002?_ga=2.192222954.1972166338.1531938679-1037540999.1531938679)

<sup>41</sup> <https://journals.lww.com/lww-medicalcare/pages/articleviewer.aspx?year=1999&issue=02000&article=00010&type=abstract>

<sup>42</sup> Analysis performed using HCUP Net Database for 2015 Hospital Discharges. <https://hcupnet.ahrq.gov/#setup>.

<sup>43</sup> Ibid.

2012 TAVR NCD, none of the registry-related questions posed by the agency asks for validation of these requirements. The latest of these studies was published in the April 2019 *New England Journal of Medicine* and analyzed data from the TVT Registry regarding procedural volumes and outcomes from 2015 through 2017.<sup>44</sup> On the other hand, the last annual report of the aggregate TVT Registry data (on patient characteristics, trends, and outcomes of TAVR procedures) was published two years ago and covers patient data only through the end of 2015.<sup>45</sup>

The April 2019 study on the volume-outcomes relationship found that hospitals in the group with the lowest volume had the highest 30-day mortality rate, at 3.19%, compared to hospitals in the group with highest volumes at 2.66%—a statistically significant difference of .53%. However, the general association was inapplicable to the current NCD conditions of coverage. The study investigators noted, “We were not able to assess whether current CMS requirements reduced mortality after TAVR or whether continuing or removing the current thresholds would affect mortality.”<sup>46</sup>

**These annual procedural volume requirements place access burdens on minority and rural beneficiary populations and service barriers to the smaller hospitals that serve them.**

Importantly, the *New England Journal of Medicine* study did identify that hospitals with lower procedural volume were more likely to be in rural areas than those with higher volume (14% versus 3%), and they treated a greater proportion of African American and Hispanic patients (12.1% versus 7.8%). This finding raises a question about whether the continued pursuit of annual procedural volume requirements may disproportionately impact treatment access for rural and minority beneficiaries.

We appreciate CMS’ spotlight on TAVR health disparities in general, and on racial, ethnic and gender differences and barriers highlighted on page 92 and 93. As noted, women have improved survival compared to men, but also have some increased risk of complications and death<sup>47</sup>. We are also pleased that issues raised in the July 2018 TAVR MEDCAC meeting acknowledging underdiagnosis and undertreatment of African Americans were noted.<sup>48</sup> However, reference to proposed flexibility in the updated annual procedural volume requirements as a way to “reduce unintended barriers” does not acknowledge that the total number of annual procedures required has, in effect, increased by tenfold, while these procedures to these underserved groups continue to lag far behind.

Additionally, section VIII “CMS Analysis” of the proposed decision examines whether to continue the NCD under CED and notes on page 81 that “the evidence is insufficient for minority populations” before concluding that “We continue to believe that the current coverage regime under CED offers the appropriate balance of quality and access, while simultaneously stimulating innovation of devices, procedural techniques, and indications for use (for subpopulations and patients with various comorbidities), and so we propose to continue CED.” ***Citing lack of evidence on minority populations as part of the rationale to continue a policy that restricts access to those same populations is circular reasoning and we ask that it be removed from this section.***

---

<sup>44</sup> [https://www.eurekalert.org/pub\\_releases/2019-04/dumc-sf040319.php](https://www.eurekalert.org/pub_releases/2019-04/dumc-sf040319.php)

<sup>45</sup> <https://www.sciencedirect.com/science/article/pii/S0735109716371753>

<sup>46</sup> [https://www.eurekalert.org/pub\\_releases/2019-04/dumc-sf040319.php](https://www.eurekalert.org/pub_releases/2019-04/dumc-sf040319.php)

<sup>47</sup> Williams, M, S Kodaki, R Hahn, K Humphries, V Nkomo, et al. 2014. Sex-Related Differences in Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis. *JACC* 63(15):1522-8.

<sup>48</sup> <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=293&NCDId=355&ncdver=1&IsPopup=y&bc=AAAAAAAAQAAA&>

African American adults experience risk factors<sup>49</sup> for aortic stenosis at greater levels and at earlier ages than whites, including cardiovascular risk factors such as high blood pressure, diabetes, and high cholesterol, and chronic kidney disease. In the United States, at any decade of life, African Americans have a higher prevalence of hypertension than any other racial and ethnic subgroups—overall, 59% of African American men, and 56% of African American women have high blood pressure.<sup>50</sup> African Americans are 1.7 times more likely to have diabetes than whites and are more likely to develop serious complications.<sup>51</sup> According to the 2018 United States Renal Data System Annual Data Report, the prevalence of chronic kidney disease among African Americans is approximately 3.5 times higher compared to whites.<sup>52</sup>

Less is known as to whether health care providers are detecting and treating aortic heart valve disease in African Americans. A study in the August 2017 *American Journal of Cardiology* found that the odds of being referred to a cardiothoracic surgeon for treatment of aortic valve disease were 54% lower in African American patients compared with whites.<sup>53</sup> Additionally, research shows that African Americans with severe aortic stenosis are 33% more likely to refuse treatment than white patients.<sup>54</sup> Yet, when they were treated with TAVR, both groups had similar three-year survival rates.<sup>55</sup>

African Americans with severe symptomatic aortic stenosis receive less surgical and transcatheter valve replacement than would be expected. While African Americans represent 13% of the US population, and 11% of the Medicare population, only 3-4% of TAVR patients<sup>56, 57</sup> and 4.8% of surgical patients<sup>58</sup> are African American.

Differences in health outcomes for African Americans compared to whites vary by type of procedure for severe symptomatic aortic stenosis. A 2018 review of more than 113,000 Medicare claims found that African Americans have significantly higher 30-day readmission rates after surgery compared to whites,

---

<sup>49</sup> <https://www.mayoclinic.org/diseases-conditions/aortic-stenosis/symptoms-causes/syc-20353139>

<sup>50</sup> [http://www.onlinejacc.org/content/71/19/e127?\\_ga=2.256562443.1631378107.1554984858-1037540999.1531938679](http://www.onlinejacc.org/content/71/19/e127?_ga=2.256562443.1631378107.1554984858-1037540999.1531938679) <https://www.heart.org/en/news/2018/05/01/more-than-half-of-all-african-americans-have-high-blood-pressure-under-new-diagnostic-guidelines?s=q%253Dmore%252520than%252520half%252520of%252520all%252520african%252520americans%252520have%252520high%252520blood%252520pressure%2526sort%253Drelevancy>

<sup>51</sup> American Diabetes Association. Treatment and Care for African Americans. Available at <http://www.diabetes.org/living-with-diabetes/treatment-and-care/high-risk-populations/treatment-african-americans.html>.

<sup>52</sup> <https://www.usrds.org/adr.aspx>.

<sup>53</sup> Rodriguez, B, P Acharya, C Salazar-Fields, A Horne. 2017. Comparison of Frequency of Referral to Cardiothoracic Surgery for Aortic Valve Disease in Blacks, Hispanics, and Whites. *Am J Cardiol* 120(3):450-5.

<sup>54</sup> Yeung, M, J Kerrigan, S Sodhi, P-H Huang, E Novak, et al. 2013. Racial Differences in Rates of Aortic Valve Replacement in Patients with Severe Aortic Stenosis. *Am J Cardiol* 112(7):991-5.

<sup>55</sup> Minha, S, I Barbash, M Magalhaes, I Ben-Dor, P Okubagzi, et al. 2015. Outcome Comparison of African-American and Caucasian Patients with Severe Aortic Stenosis Subjected to Transcatheter Aortic Valve Replacement: A single-center experience. *Catheterization Cardiovasc Interv* 85(4):640-7.

<sup>56</sup> 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. *J Am Coll Cardiol* 69(10):1215-30.

<sup>57</sup> Christian McNeely, MD, Alan Zajarias, MD, Raymond Fohitung, MD Racial Comparisons of the Outcomes of Transcatheter and Surgical Aortic Valve Implantation Using the Medicare Database *The American Journal of Cardiology*, Volume 122, Issue 3, 1 August 2018, Pages 440-445.

<sup>58</sup> Ibid.

even after adjusting for comorbidities, as well as higher unadjusted 30-day and 1-year mortality, longer length of stay, and lower likelihood of discharge to home than whites.<sup>59</sup> In the same study, race was not found to impact mortality, readmission, or discharge to home in use of TAVR.<sup>60</sup>

CMS' proposed decision acknowledges the dispute by reducing some of the volume-metric requirements. However, the proposed NCD update continues to lean on the now-debunked volume-outcomes hypothesis to justify continuation of minimum volume metrics. The modifications will exacerbate patient access issues even further.

### **Health outcomes data for individual TAVR programs collected by the CED-approved registry are kept private from the public, which impedes quality improvement**

The TVT Registry reports on aggregate data. Hospital-specific information on TAVR health outcomes is not publicly available. The TVT Registry website states that "Hospital-specific registry data is not publically [sic] available and the registry cannot provide data without written permission from the hospital to do so."<sup>61</sup>

We ask that this lack of transparency of health outcomes by facility be eliminated in the updated NCD. Under the Hospital Inpatient Quality Reporting Program, CMS collects quality data from hospitals paid under the Inpatient Prospective Payment System, with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care provided to all patients. The hospital-specific data collected through the program are available to consumers and providers on the Hospital Compare website at: <https://www.medicare.gov/hospitalcompare/search.html>. We would like to see center-specific outcomes data for in-hospital and 30-day risk-adjusted mortality, broken out by SAVR and TAVR, included on Hospital Compare.

Immediate reporting of these data are already provided in New York State. Since 1989, the New York Department of Health (DOH) has published annual data on risk-adjusted mortality following coronary artery bypass surgery by hospital and surgeon.<sup>62</sup> The state's Cardiac Surgery Reporting System (CSRS) was the first program in the country to produce public data on outcomes for cardiac surgery and is the nation's longest running program of its kind. DOH is advised in its activities by the Cardiac Advisory Committee (CAC), a group of independent, practicing cardiac surgeons, cardiologists and other professionals in related fields. The goal of DOH and the CAC is to improve the quality of care related to cardiac surgery in the state. Providing hospitals and cardiac surgeons in New York with data about their own outcomes for these procedures allows them to examine the quality of care they provide and to identify areas needing improvement, and it allows patients and family caregivers to research data on TAVR mortality outcomes in local hospitals. The program operates under the general authority of the DOH commissioner. Reporting on TAVR in New York State started in 2015 with hospital volume and moved to mortality rate reporting in 2017 by hospital for discharges from 2012-2014. The most recent

---

<sup>59</sup> Ibid.

<sup>60</sup> Ibid.

<sup>61</sup> <https://www.ncdr.com/WebNCDR/tvt/publicpage/faqs>.

<sup>62</sup> <https://www.health.ny.gov/statistics/diseases/cardiovascular/>

report on mortality rates is from February 2018 for TAVR discharges between 2013 and 2015.<sup>63</sup> **We know from the New York DOH that this can be done, and the TVT Registry should be doing it.**

Another option that we would support as an alternative would be for CMS to continue NCD under CED, with only the national registry requirement, and immediate, mandatory public reporting of both in-hospital and 30-day adjusted mortality by hospital.

**If FDA expands TAVR indications to patients at low-risk for surgery, and the CED and its program maintenance requirements remain, waiting lists at larger hospitals will lengthen and patients may die due to delays**

Aortic valve replacement (AVR), whether through open-heart surgery or TAVR, is indicated for severe symptomatic aortic stenosis, regardless of age. A seminal 1968 study on aortic stenosis found that more than half of patients will die within the next 12–18 months of symptom onset, unless the aortic valve is replaced.<sup>64</sup>

Because many patients with aortic stenosis are evaluated electively on an outpatient basis, waiting time between recommendation for aortic valve replacement and the actual intervention may place the patient at risk for progression of heart failure or death. A study in the November 2014 *Annals of Thoracic Surgery* looked at the probability of death without an intervention at 1, 3, 6, 12, and 24 months after treatment was recommended. The study found that the cumulative probability of death among patients recommended to have TAVR was 3.8% at 1 month, 10.4% at 3 months, 23.3% by six months, 27.5% at a year, and 41.1% at two years.<sup>65</sup> The study concluded that “treatment delay beyond one month for patients with AS [aortic stenosis] should be avoided,” and that “patients and physicians should proceed with AVR in patients with AS on a semi urgent, rather than elective, basis.”<sup>66</sup>

In the proposed decision, CMS designates that one surgeon (down from two in the 2012 NCD) must evaluate patient suitability for treatment. While we are pleased that this requirement was reduced, either a surgeon or cardiologist could serve this role and would lessen wait times. Maintaining a surgeon as the sole decision-maker will continue to create unnecessary bottlenecks, impacting patient access. This issue would become moot if the CED is removed.

In addition, during the past decade, recommendations for TAVR in patients with severe symptomatic aortic stenosis have been expanded to include patients with incrementally lower surgical risk. Current clinical practice has restricted the use of TAVR in patients who are at low risk and in younger patients, for whom surgery is standard therapy. The FDA is expected to approve the procedure for lower-risk patients within the next year.

With more patients eligible for this less-invasive procedure, demand will go up. This means waiting lists will be longer and patients will be at risk of dying from their disease while they wait or turning to open-

---

<sup>63</sup> [https://www.health.ny.gov/statistics/diseases/cardiovascular/heart\\_disease/docs/2013-2015\\_adult\\_cardiac\\_surgery.pdf](https://www.health.ny.gov/statistics/diseases/cardiovascular/heart_disease/docs/2013-2015_adult_cardiac_surgery.pdf)

<sup>64</sup> Ross J Jr. Braunwald E. Aortic stenosis. *Circulation* 1968;38:61-7.

<sup>65</sup> Malaisrie, S, E McDonald, J Kruse, Z Li, E McGee, et al. 2014. Mortality While Waiting for Aortic Valve Replacement. *Ann Thorac Surg* 98(5):1564-71.

<sup>66</sup> *Ibid.*

heart surgery even if they prefer TAVR and would be eligible for the less-invasive procedure. This is one more reason for CMS to consider the transition from CED to a NCD with coverage to label.

**The continuation of the CED requirement is contrary to the Administration’s “patients over paperwork” initiative and places unnecessary regulatory burdens and costs on providers that don’t improve care for patients**

We believe that the conditions for coverage in the existing NCD for TAVR do not meet CMS’ goals of putting patients first<sup>67</sup>, nor are they consistent with CMS’ desired shift from paying for volume to paying for value.<sup>68</sup> As Secretary Alex Azar stated on March 5, 2018, in his remarks on value-based transformation:

“There is no turning back to an unsustainable system that pays for procedures rather than value. In fact, the only option is to charge forward – for HHS to take bolder action, and for providers and payers to join with us. This administration and this President are not interested in incremental steps. We are unafraid of disrupting existing arrangements simply because they’re backed by powerful special interests.”

**Conclusion**

We applaud CMS’ goal to increase access for patients; however, the proposed updated NCD continues to prioritize procedural volume over equal access and quality care for all Medicare beneficiaries.

***We urge CMS to end the CED process for TAVR and transition it to a NCD with coverage to FDA-approved label.*** CMS and CAG have done an exceptional job managing the TAVR NCD under CED, despite the absence of a clear statutory foundation to support them. Extensive evidence has been developed over the last seven years to support ending the TAVR CED process and CMS can confidently declare success.

Our organizations urge CMS to phase out TAVR volume standards, and phase in hospital-based quality and outcomes data, as the primary metric for CMS TAVR coverage.

**In summary, our organizations call on CMS to develop a solid coverage policy that provides all Medicare beneficiaries with severe symptomatic aortic stenosis access to all appropriate treatments.**

This is an important opportunity for the agency to offer hope and better access to more patients and families and to put true patient-centered care into practice.

CMS may insist on keeping the TAVR NCD under CED despite the evidence that it is a reasonable and necessary alternative to open-heart surgery and despite its own guidance on the CED process. If CMS decides to do this, it should keep only the national registry requirement, and require immediate,

---

<sup>67</sup> Verma, S. June 26, 2018. “Patients Must Be at the Center” of Cost, Quality Decisions. Washington Times. Available at <https://www.washingtontimes.com/news/2018/jun/26/patients-must-be-at-the-center-of-cost-quality-dec/>

<sup>68</sup> Verma, S. May 7, 2018. Remarks by CMS Administrator Seema Verma at the American Hospital Association Annual Membership Meeting. CMS.gov Available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-05-07.html>

mandatory public reporting of both in-hospital and 30-day adjusted mortality by individual hospitals. Any additional requirements would impede access and potentially harm beneficiaries.

Thank you for the work you do to improve the health and well-being of our nation's older adults, and for considering our views.

Sincerely,

**Alliance for Aging Research**

**Alliance for Patient Access**

**Association of Black Cardiologists**

**Caregiver Action Network**

**HealthyWomen**

**Heart Valve Voice US**

**Mended Hearts**

**Men's Health Network**

**National Black Nurses Association**

**National Hispanic Medical Association**

**National Medical Association**

**National Minority Quality Forum**

**Partnership to Advance Cardiovascular Health**

**RetireSafe**