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Joanna Baldwin
Interim Director, Coverage and Analysis Group (CAG)
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

RE: Transcatheter Aortic Valve Replacement National Coverage Analysis - CAG-00430R2

Dear Ms. Baldwin,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Transcatheter Aortic Valve Replacement (TAVR) National Coverage Analysis (NCA). Founded in 1964, STS is a not-for-profit organization representing more than 7,800 surgeons, researchers, and allied healthcare 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.

This document outlines key considerations regarding the evolving use of TAVR in the context of the current NCA. As access to TAVR expands, it is critical that coverage policy continues to prioritize patient safety and high-quality, evidence-based care. The following points summarize our positions.

- **Completion of Coverage with Evidence Development (CED):**
  - CED should continue until there is adequate evidence to inform the lifetime management of patients with aortic stenosis (AS), including long-term outcomes, device durability, and the need for repeat interventions. As indications expand and treated populations and care settings evolve, continued participation in the STS/ACC Transcatheter Valve Therapy Registry™ (TVT-R) remains essential to generate real-world data that ensure coverage decisions keep pace with clinical practice and patient needs.
- **Expanded TAVR Indications:**
  - We support a measured, evidence-based approach to treating asymptomatic AS. While emerging trial data suggests potential benefit in select patients, treatment should be limited to carefully defined populations evaluated by a multidisciplinary Heart Team, with shared decision-making and continued evidence development to avoid inappropriate expansion and overtreatment.
- **Patient Access and Geographic Equity**
  - While limited geographic access to care issues exist, the priority should remain ensuring safe access to TAVR rather than decentralizing care. Maintaining established centers with multidisciplinary Heart Teams and on-site surgical backup is critical to protect patients, minimize procedural complications, and enable timely rescue in the event of adverse events.

Coverage with Evidence Development

STS has significant concern regarding the proposal to remove CED from the TAVR National Coverage Determination (NCD). While we recognize that, by law, CED is intended to sunset, STS does not believe that the current state of TAVR warrants the removal of this important safeguard. CED has played a critical role in ensuring patient safety by supporting the systematic collection of real-world evidence, monitoring outcomes, and identifying areas for improvement in TAVR procedures and technology innovation. Removing CED at this juncture will compromise our ability to assess expanded indications and detect emerging risks, address gaps in knowledge, and maintain the highest standards of care for Medicare beneficiaries. The removal of CED raises several critical issues, which we will detail in the following sections. We urge CMS to carefully consider the implications of this change for patient safety and the broader healthcare system.

Real-World Evidence Needed for New Indications

CMS is considering additional coverage for asymptomatic AS patients within the TAVR NCD due to evidence that early intervention of aortic valve replacement (AVR) reduces the risk of death, stroke, or unplanned cardiovascular hospitalization. While observations that some asymptomatic patients with severe AS may be at higher risk and benefit from early TAVR intervention, American College of Cardiology (ACC)/American Heart Association (AHA) clinical guidelines state that intervention is generally reserved for patients with left ventricle ejection fraction (LVEF) <50%, abnormal exercise test, or other high-risk features (e.g., very severe AS, rapid progression, elevated B-type Natriuretic Peptide (BNP)). Routine TAVR in asymptomatic patients is not recommended, underscoring the need for cautious, individualized, Heart Team-based decision making supported by prospective data collection.[1]

The natural history of truly asymptomatic AS is characterized by a relatively low short-term mortality risk when patients are carefully monitored. Data from the Heart Valve Clinic demonstrate that among patients with asymptomatic aortic stenosis followed longitudinally, the annual rate of sudden cardiac death was approximately 2.5 per 1,000 patients, reflecting a very low absolute risk under contemporary management.[2] These findings underscore that, in the absence of symptoms or high-risk features, watchful waiting with structured surveillance is a safe and effective strategy for many patients. If TAVR coverage is expanded beyond current guideline-supported indications, CED is necessary to distinguish patients who meaningfully benefit from early intervention from those for whom procedural risk (i.e., thrombosis, infection, prosthetic heart valve disease, and device failure) may outweigh the potential benefits.

Evidence supporting early TAVR in asymptomatic patients remains limited. The EARLY TAVR trial demonstrated a reduction in a composite endpoint driven largely by cardiovascular hospitalizations, but it did not show a reduction in all-cause mortality. The trial has also been subject to critique related to endpoint selection, crossover from surveillance to intervention, and questions regarding generalizability to routine clinical practice. These limitations are particularly important when considering patients outside the narrowly defined trial population, reinforcing the need for ongoing evidence generation through CED if coverage is broadened.

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[1] Lindman, B, Dweck, M, Lancellotti, P. et al. Management of Asymptomatic Severe Aortic Stenosis: Evolving Concepts in Timing of Valve Replacement. J Am Coll Cardiol Img. 2020 Feb, 13 (2_Part_1) 481–493. https://doi.org/10.1016/j.jcmg.2019.01.036

[2] Lancellotti P, Magne J, Donal E, et al. Outcomes of patients with asymptomatic aortic stenosis followed up in heart valve clinics. *JAMA Cardiol.* 2018;3(11):1060-1068. doi:10.1001/jamacardio.2018.3152

In the EARLY TAVR trial, early intervention reduced a composite endpoint driven largely by cardiovascular hospitalizations but did not reduce all-cause mortality.[3] An accompanying editorial by Nishimura underscored this limitation, emphasizing that in the absence of symptoms, patients cannot experience symptomatic or quality-of-life improvement and therefore derive no perceptible benefit from early valve replacement.[4] As noted in the editorial, intervening in asymptomatic patients raises fundamental questions when treatment neither prolongs life nor improves how patients feel. Importantly, the generalizability of the trial findings is further limited by restricted patient diversity, including the enrollment of relatively few women, a population known to have distinct valvular anatomy, presentation patterns, and outcomes following valve intervention.[5,6] CED would provide a valuable mechanism to address these evidence gaps by capturing outcomes across broader, more representative populations.

Other randomized evidence evaluating early intervention strategies in asymptomatic patients, such as the EVOLVED trial, failed to demonstrate a significant benefit on hard clinical outcomes, underscoring persistent uncertainty regarding optimal timing of intervention.[7] Moreover, other trials frequently cited in support of early treatment, RECOVERY and AVATAR, evaluated surgical aortic valve replacement (SAVR) rather than TAVR. While these studies provide valuable insight into the potential role of early surgery in carefully selected patients, their findings cannot be directly extrapolated to transcatheter approaches, given meaningful differences in patient selection, procedural risk, durability considerations, and long-term management.[8]
If CMS elects to include asymptomatic AS patients in the TAVR NCD, CED is necessary to ensure that expansion is guided by real-world evidence rather than a single trial with acknowledged limitations. Particular caution is warranted for patients outside the EARLY TAVR trial population, where uncertainty regarding benefit is greatest. Importantly, patient selection should be driven not by chronological age alone, but by projected life expectancy, comorbidity burden, and anticipated durability needs, factors best assessed by a multidisciplinary Heart Team. Continued CED would allow CMS to monitor outcomes, refine selection criteria, and ensure that early intervention improves survival and long-term patient-centered outcomes without exposing patients to unnecessary procedural risk.

Additionally, a California statewide analysis of AVR in patients ≤60 years old underscores why continued CED for TAVR is essential to protect patients in expanded populations. Using statewide administrative data from 2013–2021, investigators found that the use of TAVR in patients under 60 increased dramatically, from just over 7% to nearly 46% by 2021.[9] This is despite professional guidelines recommending SAVR for younger, lower-risk patients due to concerns about long-term valve durability and lifetime management of aortic valve

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[3] Généreux P, Schwartz A, Oldemeyer JB, et al; EARLY TAVR Trial Investigators. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. *N Engl J Med.* 2025;392(3):217-227. doi:10.1056/NEJMoa2405880
[4] Nishimura RA. Early transcatheter aortic-valve replacement for asymptomatic aortic stenosis—proceed with caution. *N Engl J Med.* 2025;392(3):287-289. doi:10.1056/NEJMe2409911
[5] Généreux P, Schwartz A, Oldemeyer JB, et al; EARLY TAVR Trial Investigators. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. *N Engl J Med.* 2025;392(3):217-227. doi:10.1056/NEJMoa2405880
[6] Chandrasekhar J, Dangas G, Mehran R. Sex differences in aortic stenosis and transcatheter aortic valve replacement. *J Am Coll Cardiol.* 2017;69(22):2733-2748. doi:10.1016/j.jacc.2017.03.552
[7] Loganath K, Craig NJ, Everett RJ, et al. Early Intervention in Patients With Asymptomatic Severe Aortic Stenosis and Myocardial Fibrosis: The EVOLVED Randomized Clinical Trial. *JAMA*. 2025;333(3):213-221. doi:10.1001/jama.2024.22730
[8] Ahmad Y, Howard JP, Seligman H, et al. Early Surgery for Patients With Asymptomatic Severe Aortic Stenosis: A Meta-Analysis of Randomized Controlled Trials. *J Soc Cardiovasc Angiogr Interv*. 2022;1(4):100383. Published 2022 May 25. doi:10.1016/j.jscai.2022.100383
[9] Egorova N, et al. *Guidelines vs Practice: Surgical Versus Transcatheter Aortic Valve Replacement in Adults ≤60 Years.* Analysis of California Department of Health Care Access and Information data showed TAVR use in patients aged ≤60 increased from 7.2% in 2013 to 45.7% in 2021. Published 2025.

disease. This rapid expansion of TAVR in young patients reflects substantial off-label use of TAVR outside the populations studied in pivotal clinical trials, highlighting how quickly practice patterns can outpace the evidence base.

Importantly, the study did not merely document utilization trends, it demonstrated potential patient harm. In propensity-matched analyses, younger patients who underwent TAVR had worse long-term survival compared with those who received SAVR, raising serious concerns about exposing younger patients to therapies without adequate long-term data. These findings illustrate the very risk CED is designed to address; when coverage expands without ongoing evidence generation and guardrails, procedures may be used in populations where safety and effectiveness are uncertain, putting current and future Medicare beneficiaries at heightened risk. CED ensures that access to TAVR remains tied to systematic data collection, guideline-concordant decision-making, and continuous evaluation of outcomes, helping prevent inappropriate off-label use and safeguarding patients.

These concerns are further reinforced by national data from the TVT-R, which show that patients younger than 65 years represent a small but growing cohort of TAVR recipients in U.S. practice. Registry analyses indicate that these younger patients often have a higher burden of comorbidities and experience worse clinical outcomes compared with older TAVR patients.[10] Taken together, the California and TVT-R findings demonstrate the critical role of CED in ensuring that access to TAVR remains linked to systematic data collection, guideline-concordant decision-making, and continuous outcome evaluation—particularly for younger patients, where inappropriate off-label use may have profound and lasting implications for patient safety and long-term outcomes.

Improve Access to Care through CED

Criticism that CED delays or restricts access to TAVR overlooks the critical role that CED plays in expanding access responsibly while protecting patient safety. The most effective way to identify, monitor, and address gaps in access to care is through systematic collection and analysis of real-world evidence. By capturing detailed data on patient characteristics, treatment patterns, outcomes, and site-level availability, CED enables policymakers and clinicians to accurately identify where disparities exist, assess whether access barriers are improving, and detect new or unforeseen challenges as clinical practice evolves. Without continued data collection, it becomes impossible to determine whether access concerns have truly been resolved or whether certain patient populations are being left behind, undermining efforts to ensure equitable care. Importantly, the history of TAVR demonstrates that CED and the TVT-R have facilitated, not hindered, innovation and access to break through technologies. The TVT-R has supported the safe adoption of successive generations of transcatheter valve technology, informed over 23 regulatory decisions, and enabled expansion of TAVR to broader risk populations based on high-quality evidence. Far from restricting care, CED has provided the framework that allowed TAVR to move rapidly from a niche therapy for high-risk patients to a widely available, lifesaving treatment while maintaining accountability and continuous quality improvement.

Concerns that CED limits access to care are not supported by current infrastructure data. There is only a modest differential between the number of hospitals performing TAVR and those only performing cardiac surgery nationwide, with approximately 870 TVT-R participating sites compared with 1,000 Adult Cardiac Surgery Database (ACSD) participants.

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[10] Coylewright M, Grubb KJ, Arnold SV, et al. Outcomes of Balloon-Expandable Transcatheter Aortic Valve Replacement in Younger Patients in the Low-Risk Era. *JAMA Cardiol*. 2025;10(2):127-135. doi:10.1001/jamacardio.2024.4237

Additionally, concerns that geographic access to TAVR remains inadequate are not supported by available national data. An analysis of the TVT-R published in *JAMA Cardiology* demonstrated that access to TAVR centers is already widespread across the United States. Among patients who underwent successful TAVR, the median driving time to the implanting center was just 35 minutes (interquartile range, 20–70 minutes), indicating that the vast majority of patients are able to receive care within a reasonable travel distance.[11] These findings suggest that TAVR availability largely parallels existing cardiac care infrastructure and that significant geographic access gaps are uncommon.

Experience from the expansion of other advanced cardiac services further supports this conclusion. Data from the National Cardiovascular Device Registries and related geographic analyses of Percutaneous Coronary Intervention program growth show that new procedural centers frequently open in close proximity to existing facilities, concentrating capacity in already well-served markets and yielding only modest gains in population access.[12] This pattern suggests that indiscriminate expansion of TAVR sites is unlikely to meaningfully improve geographic access, while risking dilution of procedural volume and fragmentation of multidisciplinary care. This demonstrates that TAVR access is broadly aligned with existing cardiac care capacity and that CED requirements have not created a significant structural barrier to care. In fact, rather than slowing adoption, CED has facilitated and accelerated the responsible diffusion of TAVR by providing a clear, transparent framework that supported regulatory confidence, informed successive coverage expansions, and enabled timely access for eligible patients as evidence matured. Taken together, these considerations underscore that CED is not a mechanism to delay treatment, but rather a proven approach to expand access thoughtfully, identify and correct disparities, and ensure that patients receive evidence-based, high-quality care as technology and indications continue to evolve.

To further reduce any perceived burden associated with CED data collection for participating hospitals, STS and ACC have implemented ongoing processes to minimize data collection demands while preserving data quality and clinical value. The STS and ACC regularly review and refine the TVT-R case report forms to identify opportunities to eliminate low-value data elements, streamline workflows, and align registry requirements with evolving clinical practice and regulatory needs.

In parallel, the registries are working with partners to develop technology-enabled solutions that automate data abstraction directly from electronic health records (EHRs), reducing the need for manual data entry and associated staff time. Together, these initiatives ensure that participation in CED remains efficient and sustainable for hospitals, while continuing to generate high-quality real-world evidence that supports patient safety, program oversight, and responsible innovation in TAVR care.

<u>Public Safety at Risk for Medicare Beneficiaries</u>

Beyond issues of access, eliminating CED poses significant risks to patient safety, particularly for a complex, rapidly evolving technology such as TAVR as clinical indications continue to expand. Although transcatheter aortic valves have not been subject to a device recall to date, the history of cardiac implantable devices demonstrates why continued, systematic surveillance is essential when novel technologies are applied to

[11] Marquis-Gravel G, Stebbins A, Kosinski AS, et al. Geographic access to transcatheter aortic valve replacement centers in the United States: insights from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. *JAMA Cardiol.* 2020;5(9):1-6. doi:10.1001/jamacardio.2020.1725

[12] Vemulapalli S, Dai D, Mulukutla S, et al. Hospital procedural volume and outcomes of percutaneous coronary intervention in the United States: insights from the NCDR CathPCI Registry. *Circulation.* 2016;134(1):55-64. doi:10.1161/CIRCULATIONAHA.115.019839

broader and lower-risk populations. The Government Accountability Office analyses of high-risk medical technologies showed that cardiovascular devices like heart valves and pacemakers represented 16% of all medical device recalls between 2020-2024, the highest of any one medical specialty area.[13] As TAVR use moves beyond its original, higher-risk populations and into new indications such as asymptomatic aortic stenosis, CED provides the critical infrastructure needed to detect early safety signals related to device performance, durability, or failure in real-world practice. Without a robust national evidence framework like CED, emerging risks may be identified too late, potentially exposing large numbers of patients to avoidable harm and undermining confidence in responsible technology adoption.

These risks are amplified by growing concerns about lifetime valve management, especially in younger and lower-risk patients. Emerging evidence suggests that valve-in-valve strategies may not provide durable long-term solutions, as second valves often demonstrate reduced lifespan and higher risk of patient-prosthesis mismatch.[14,15] Data also indicate that a treatment sequence of TAVR followed by SAVR may be detrimental, with more complex surgery and worse outcomes compared with initial SAVR in appropriate patients.[16] Consistent with these concerns, surgical aortic valve replacement after prior TAVR is now the fastest growing reoperative valve procedure captured in the ACSD.[17] These trends underscore the need for continued, systematic data collection to better understand long-term outcomes, procedural sequencing, and the true lifetime implications of early TAVR use.

Public safety concerns are further heightened by recent policy shifts, including the elimination of the inpatient-only (IPO) list in the CMS Federal Year 2026 Inpatient Prospective Payment System final rule. STS has significant concerns with the finalization of the IPO list and the momentum that allows for the potential expansion of TAVR into ambulatory surgical centers that may lack on-site surgical backup. As TAVR moves into lower-acuity environments, the risk of fragmented care and delayed rescue in the event of catastrophic complications increases. Notably, recent data demonstrate that lowering procedural volume thresholds and moving away from coordinated Heart Team–based care are associated with higher complication rates and worse patient outcomes.[18] These findings directly reinforce the rationale underlying the TAVR multi-society consensus statement, which established minimum institutional and operator volume requirements to ensure adequate experience, team readiness, and infrastructure for managing procedural complexity and

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[13] https://files.gao.gov/reports/GAO-26-107619/index.html?_gl=1*17pw1d8*_ga*MjA0NjcwNzIyOS4xNzY2MDgxMDQ2*_ga_V393SNS3SR*czE3NjYwODEwNDYkbzEkZzEkdDE3NjYwODEwNjckajM5JGwwJGgw

[14] Herrmann, H, Daneshvar, S, Fonarow, G. et al. Prosthesis–Patient Mismatch in Patients Undergoing Transcatheter Aortic Valve Replacement: From the STS/ACC TVT Registry. JACC. 2018 Dec, 72 (22) 2701–2711. https://doi.org/10.1016/j.jacc.2018.09.001

[15] Testa L, Casenghi M, Criscione E, et al. Prosthesis-patient mismatch following transcatheter aortic valve replacement for degenerated transcatheter aortic valves: the TRANSIT-PPM international project. *Front Cardiovasc Med*. 2022;9:931207. Published 2022 Jul 29. doi:10.3389/fcvm.2022.931207

[16] Jawitz OK, Gulack BC, Grau-Sepulveda MV, et al. Reoperation After Transcatheter Aortic Valve Replacement: An Analysis of the Society of Thoracic Surgeons Database. *JACC Cardiovasc Interv*. 2020;13(13):1515-1525. doi:10.1016/j.jcin.2020.04.029

[17] Bowdish ME, Habib RH, Kaneko T, Thourani VH, Badhwar V. Cardiac Surgery After Transcatheter Aortic Valve Replacement: Trends and Outcomes. *Ann Thorac Surg*. 2024;118(1):155-162. doi:10.1016/j.athoracsur.2024.03.024

[18] Kumbhani DJ, Girotra S, Dong H, et al. Contemporary Operator Procedural Volumes and Outcomes for TAVR and MTEER in the US. JAMA Cardiol. Published online January 08, 2026. doi:10.1001/jamacardio.2025.5645

complications.[19] The consensus statement volume requirements are not arbitrary barriers to access, but evidence-informed safeguards designed to preserve quality and patient safety as TAVR is adopted across diverse care settings. Maintaining these programmatic requirements is essential, particularly as TAVR expands into new indications and lower-risk populations.

Preservation of the multidisciplinary Heart Team model is therefore essential to maintaining high-quality, patient-centered care as TAVR use continues to expand. The Heart Team unites cardiac surgeons, interventional cardiologists, imaging experts, anesthesiologists, and other cardiovascular clinicians to support thoughtful, guideline-aligned patient selection. This multidisciplinary approach also enables careful procedural planning for complex anatomy and long-term valve management, while ensuring that potential complications are addressed efficiently through coordinated access to the full range of cardiovascular expertise. Importantly, this collaborative model has been central to the successful development and diffusion of TAVR itself, serving as a historical example of how novel cardiovascular devices can be safely introduced through rigorous evidence generation, registry-based oversight, and shared clinical accountability. This is particularly critical as TAVR is considered for younger patients, anatomically challenging conditions, and emerging indications where the balance of risks and benefits may be less certain and long-term implications are substantial. Continued CED provides the infrastructure needed to capture outcomes across care settings, monitor safety as practice patterns evolve, and ensure that expanded access does not come at the expense of patient safety.

New Technology Becoming Available

As new transcatheter technologies continue to emerge, CED becomes increasingly essential to ensure patient safety and optimize clinical outcomes. For example, trials are now evaluating TAVR in patients with bicuspid aortic valves, a population historically excluded from pivotal TAVR studies due to anatomic complexity and concerns about procedural durability and complications.[20] Systematic real-world evidence collection is critical in this context to monitor device performance, procedural success, and long-term outcomes outside the controlled trial environment, providing insights into the safety and effectiveness of TAVR in anatomically challenging patients.

Similarly, novel transcatheter devices to treat aortic regurgitation are entering clinical development and early adoption.[21] Unlike stenotic valves, aortic regurgitation presents unique hemodynamic challenges that may influence valve seating, paravalvular leak, and long-term durability.[22] Without the structured oversight and data capture afforded by CED, it would be difficult to identify early safety signals, procedural limitations, or patient selection criteria necessary to guide broader adoption. In both scenarios, CED ensures that the introduction of innovative therapies is accompanied by rigorous outcome monitoring, continuous quality improvement, and evidence-based decision-making, protecting patients while supporting responsible innovation in structural heart disease.

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[19] Bavaria JE, Tommaso CL, Brindis RG, et al. 2018 AATS/ACC/SCAI/STS expert consensus systems of care document: operator and institutional recommendations and requirements for transcatheter aortic valve replacement. *J Am Coll Cardiol.* 2019;73(3):340-374. doi:10.1016/j.jacc.2018.07.002

[20] Halim SA, Edwards FH, Dai D, et al. Outcomes of Transcatheter Aortic Valve Replacement in Patients With Bicuspid Aortic Valve Disease: A Report From the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. *Circulation*. 2020;141(13):1071-1079. doi:10.1161/CIRCULATIONAHA.119.040333

[21] https://www.acc.org/Latest-in-Cardiology/Clinical-Trials/2025/03/27/17/51/align-ar

[22] Brouillard P, Diallo EH, Ben Ali W, Kouz R. The Next Chapter in TAVR: Innovations and the Road Ahead. J Clin Med. 2025 Jun 25;14(13):4504. doi: 10.3390/jcm14134504. PMID: 40648878; PMCID: PMC12249560.

STS strongly urges CMS to maintain CED for TAVR. CED has been essential for safeguarding patient safety, supporting systematic data collection, and guiding responsible expansion of TAVR to new populations. Removing CED now could compromise the ability to monitor outcomes, address emerging risks, and ensure equitable access to high-quality care. As TAVR indications and technologies continue to evolve, ongoing evidence generation remains critical to protect patients and support innovation. Ongoing evidence generation supports best practices for structural heart disease management.

Thank you for considering these comments. We appreciate CMS's consideration and remain committed to collaborating on policies that guarantee safe, effective, and accessible aortic valve therapies for all patients. For additional information or clarification, please contact Molly Peltzman, Associate Director of Health Policy, at mpeltzman@sts.org.

Sincerely,

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President