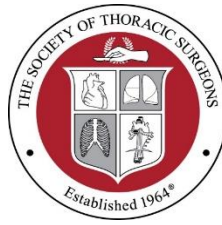


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June 10, 2024

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 and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes [CMS-1808-P]

Dear Administrator Brooks-LaSure,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Fiscal Year (FY) 2025 Inpatient Prospective Payment System (IPPS) Proposed Rule. Founded in 1964, STS is a not-for-profit organization representing more than 7,700 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.

### **Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights**

#### **Changes to MS-DRG Classifications and Relative Weights**

*CMS performed an analysis to determine whether changes are needed to MS-DRGs. This includes the 5 mandatory criteria that CMS uses to determine whether the cases in a given MS-DRG require complication or comorbidity (CC) or major complication or comorbidity (MCC) subdivisions. In applying its methodology and appropriate data for FY 2025, CMS noted the policy it finalized in FY 2021 "to include the non-CC subgroup for a three-way severity level split (and potential two-way splits). Due to the Public Health Emergency (PHE), in FYs 2022 and 2023, CMS delayed the application of non-CC subgroup criteria to existing MS-DRGs. CMS proposes to again delay the application of non-CC subgroup criteria for FY 2025.*

STS agrees with and appreciates CMS' proposal to continue to delay application of the non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split for FY 2025 as they continue to consider the public comments received in response to the FY 2024 rulemaking.

## Changes to Specific MS-DRG Classifications

*Major Diagnostic Category (MDC) 05 (Diseases and Disorders of the Circulatory System)*

### Requests to Modify GROUPER Logic: MS-DRG 212 Concomitant Aortic and Mitral Valve Procedures

*CMS received two requests to modify the GROUPER Logic of new MS-DRG 212 (Concomitant Aortic and Mitral Valve Procedures). The first request was to change the GROUPER Logic to be defined by cases reporting procedure codes describing a single open mitral or aortic valve replacement/repair (MVR or AVR) procedure, plus an open coronary artery bypass graft procedure (CABG) or open surgical ablation or cardiac catheterization procedure, plus a second concomitant procedure. The second was to redefine the procedure code list describing the performance of a cardiac catheterization by either removing the ICD-10-PCS codes that describe plain radiography of coronary artery codes from the logic list or adding ICD-10-PCS procedure codes that involve computed tomography (CT) or magnetic resonance imaging (MRI) scanning using contrast to the list and adding ICD-10-PCS procedures codes that describe endovascular valve replacement or repair procedures to the list.*

Consistent with our previous comments to the FY 2024 IPPS Proposed Rule and separately shared with CMS, STS recommends that CMS consider changing the definition of MS-DRG 212 to Concomitant Aortic or Mitral Valve Procedures to recognize the increased complexity resource utilization of a single open AVR or MVR procedure performed in addition to another concomitant procedure including CABG, open surgical ablation or intraoperative pVAD. STS appreciates CMS' recognition of increased resource utilization when valve procedures are performed concomitantly with open surgical ablation procedures by the creation of new MS-DRG 212. However, we still believe that MS-DRG 212 should be changed to recognize open aortic valve repair or replacement procedure or a mitral valve repair or replacement procedure when performed with any of the other concomitant procedures to better account for increased resource utilization within a wider range of patients.

STS also recommends that CMS move the ICD-10-PCS with the root operations of "creation", "release", "restriction" and "supplement" which represent forms of aortic or mitral valve repairs from the list of Concomitant Operating Room Procedures to the appropriate list of aortic valve or mitral valve procedures. Specifically, moving the following ICD-10-PCS codes from the concomitant operating room procedures list to the aortic valve procedures list:

024F07J, 024F08J, 024F0JJ, 024F0KJ, 02NF0ZZ, 02UF07Z, 02UF08J, 02UF08Z, 02UF0JJ, 02UF0JZ, 02UF0KJ, 02UF0KZ, 02UF47J, 02UF47Z, 02UF48J, 02UF48Z, 02UF4JJ, 02UF4JZ, 02UF4KJ and 02UF4KZ

Additionally, moving the following ICD-10-PCS codes from the concomitant operating room procedures list to the mitral valve procedures list:

024G072, 024G082, 024G0J2, 024G0K2, 02NG0ZZ, 02UG07E, 02UG07Z, 02UG08E, 02UG08Z, 02UG0JE, 02UG0JZ, 02UG0KE, 02UG0KZ, 02UG47E, 02UG47Z, 02UG48E, 02UG48Z, 02UG4JE, 02UG4JZ, 02UG4KE, 02UG4KZ, 02VG0ZZ and 02VG4ZZ.

We support CMS' review and recognition of other changes to the MS-DRG 212 GROUPER Logic to appropriately account for increases in resource utilization. While we appreciate that more time is required to obtain data for MS-DRG 212 before making any changes to the GROUPER Logic, we

encourage CMS to keep the above-mentioned factors in mind as data is collected and analyzed. Specifically, we would like to see how the data may support changing MS-DRG 212 to reflect single aortic or mitral valve repair or replacement with concomitant procedures. As with the proposed MS-DRG 317 for FY 2025, STS encourages CMS to continue to review and create broader, more inclusive, supplemental payment mechanisms to facilitate the incremental increases in resource utilization when two major procedures are performed during the same hospital admission.

#### Concomitant Left Atrial Appendage Closure (LAAC) and Cardiac Ablation

*For FY 2025, CMS is proposing to create a new base MS-DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation) for cases reporting a LAAC procedure and a cardiac ablation procedure in MDC 05 because clinically, greater resources are required when both procedures are performed. The nine ICD-10-PCS procedure codes that describe LAAC procedures and 27 ICD-10-PCS procedure codes that describe cardiac ablation identified by CMS will be in the logic for assignment of cases to the proposed new MS-DRG.*

STS supports CMS' proposal to create new MS-DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation) to appropriately capture the increased resource utilization when left atrial appendage closure and cardiac ablation are performed concomitantly.

However, we request that the three chordae tendineae ICD-10-PCS codes (02590ZZ, 02593ZZ and 02594ZZ) be removed from the list of cardiac ablation procedures for MS-DRG 317. The inclusion of these codes is inappropriate as the chordae tendineae would not be destroyed in relation to cardiac ablation procedures. Instead, they would be performed in relation to cardiac valve repair or replacement procedures. While it is unlikely that these would be the only procedures performed, if so, assigning them to MS-DRG 212 (Concomitant Aortic and Mitral Valve Procedures) or MS-DRGs 216-221 (Cardiac valve and other major cardiothoracic procedures) would be more appropriate. STS also suggests that CMS add ICD-10-PCS code 02583ZF (Destruction of conduction mechanism using irreversible electroporation, percutaneous approach for pulse field ablation) to the list of cardiac ablation codes for MS-DRG 317.

Additionally, in reviewing the MS-DRG Definitions Manual and Software FY 2025 – Version 42 Test GROUPER – DRAFT file for FY 2025 IPPS/LTCH PPS Proposed Rule for MS-DRG 317, STS noticed that several ICD-10-PCS open and percutaneous endoscopic approach codes contained an asterisk designating them as non-operating room procedures. This included all of the open and percutaneous endoscopic ICD-10-PCS codes listed under the left atrial appendage closure procedures, the first condition that must be met for the MS-DRG, and two of the ICD-10-PCS codes listed under the cardiac ablation procedures. This includes the following ICD-10-PCS codes:

- 02L70CK\* Occlusion of Left Atrial Appendage with Extraluminal Device, Open Approach,
- 02L70DK\* Occlusion of Left Atrial Appendage with Intraluminal Device, Open Approach,
- 02L70ZK\*, Occlusion of Left Atrial Appendage, Open Approach,
- 02570ZK\* Destruction of Left Atrial Appendage, Open Approach,
- 02L74CK\* Occlusion of Left Atrial Appendage with Extraluminal Device, Percutaneous Endoscopic Approach,
- 02L74DK\* Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Endoscopic Approach,
- 02L74ZK\* Occlusion of Left Atrial Appendage, Percutaneous Endoscopic Approach, and

- 02574ZK\* Destruction of Left Atrial Appendage, Percutaneous Endoscopic Approach.

Note that we include the percutaneous endoscopic approach codes since these would include thoracoscopic left atrial appendage closure and thoracoscopic cardiac ablation procedures.

STS is concerned with the non-operating room (OR) designation of these codes and would suggest identifying them as OR procedures to account for the appropriate resource utilization. We recognize that CMS is planning to conduct a comprehensive, systematic review of the ICD-10-PCS and the process for determining whether a procedure is considered an OR procedure. STS agrees with CMS and others that there are no easy rules for determining when certain surgeries should be categorized as OR procedures versus non-OR procedures. However, we believe that it is reasonable that those typically performed as inpatient procedures (e.g., those included on the inpatient only list) have inherent factors that qualify them as procedures that would require greater resource utilization. By their very nature, these tend to be higher risk procedures that will typically require the use of a traditional or hybrid OR, the recovery room and usually (but not always) general anesthesia.

We agree that there are many other factors that can contribute to increased resource consumption in addition to patient status at the time of the procedure and the location where the procedure is performed. However, the factors that the CMS physician panels historically used to identify increased consumption of hospital resources, such as the OR are still relevant. The additional resources required for each procedure should also be considered. This may include the use of high-cost equipment or supplies for the procedure, additional equipment and/or personnel that is required to be available for the procedures (e.g. perfusionist and equipment for procedures that require cardiopulmonary bypass), the length of stay typically associated with a procedure, and the patient's comorbidities and risk factors. All of these factors can impact resource utilization.

Specific to the codes identified as non-OR procedures related to MS-DRG 317, LAAC and cardiac ablation procedures that require an "open approach" require a transthoracic approach (median sternotomy, thoracotomy or subxiphoid) that will require use of an OR, general anesthesia and the recovery room at a minimum. Additionally, many of these procedures will require use of specialized equipment or devices related to the method of LAAC and/or cardiac ablation. LAAC or cardiac ablation procedures that fall under the codes with a percutaneous endoscopic approach will typically include those that are performed via a thoracoscopic approach. As with the open approaches for these procedures, thoracoscopic LAAC and cardiac ablation procedures are typically performed as inpatient procedures in the OR requiring general anesthesia and the recovery room along with the use of specialized equipment and devices related to the thoracoscopy, ablations and LAACs. As such, STS recommends that CMS designate the ICD-10-PCS open and percutaneous endoscopic approach codes identified above as OR procedures under MS-DRG 317.

#### Neuromodulation Device Implant for Heart Failure (Barostim™ Baroreflex Activation Therapy)

*For FY 2025, based their review of the clinical issues and the claims data, and to better account for the resources required, CMS is proposing to reassign all cases with one of the following ICD-10-PCS code combinations describing the implantation of a BAROSTIM™ system, to MS- DRG 276, even if there is no MCC reported:*

- *0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of stimulator lead into right internal carotid artery, percutaneous approach); and*

- *OJH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with O3HL3MZ (Insertion of stimulator lead into left internal carotid artery, percutaneous approach).*

*CMS is also proposing to change the title of MS-DRG 276 from “Cardiac Defibrillator Implant with MCC” to “Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator” to reflect the proposed modifications to MS-DRG assignments.*

STS supports CMS’ proposal to move the ICD-10-PCS codes used to report implantation of a BAROSTIM™ system, to MS- DRG 276 even if there is no MCC reported to better account for the resources required for the procedure. STS also agrees that although there are procedural differences in the procedures that are assigned to MS-DRG 276, the implantation of the BAROSTIM™ system is more clinically coherent with those procedures assigned to MS-DRG 276 because they share the indication of heart failure and require an implant to manage the indication. In addition, STS agrees with CMS’ proposal to change the title of MS-DRG 276 to “Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator” to better reflect the proposed modifications to the MS-DRG assignments.

#### Endovascular Cardiac Valve Procedures

*For FY 2025, CMS has received a request to delete MS-DRGs 266 and 267 and reassign transcatheter aortic valve replacement (TAVR) or repair supplement procedures to the following MS-DRGs (to where surgical aortic valve replacement [SAVR] is currently assigned). CMS reminded stakeholders that “MS-DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources and are not intended to be utilized as a tool to incentivize the performance of certain procedures.” Therefore, CMS proposes to maintain the current MS-DRG assignments for SAVR and TAVR.*

STS strongly supports CMS’ recommendation to maintain the current structure of MS-DRGs 266 and 267 for FY 2025. It is unclear to STS why the requestor would imply that there is any type of bias in patient selection of surgical cardiac valve replacement and repair procedures over endovascular cardiac valve replacement and supplement procedures. All the endovascular cardiac valve replacement and supplement procedures have associated NCDs, that require that cardiologists and cardiac surgeons assess the patient and work with the heart team to determine the most appropriate treatment for the patient. The decision to have endovascular cardiac valve replacement and supplement procedures or surgical cardiac valve replacement or repair procedures is typically made by the heart team based on the patient’s individualized risk-benefit and associated factors such as the patient’s age, surgical risk, frailty, valve morphology, and presence of concomitant valve disease or coronary artery disease. STS has worked closely with the American College of Cardiology (ACC) and the Society for Cardiovascular Angiography & Interventions (SCAI) and CMS to ensure that the patient’s clinical assessment includes that of both a cardiac surgeon and a cardiologist and their assessments are reviewed by the heart team to ensure the patient is selected for the most appropriate cardiac valve intervention based on the clinical guidelines and the patient’s risk factors, not payment.

STS also agrees with CMS that although both types of cardiac valve interventions treat the same type of disease, the work and resource utilization associated with the procedures is significantly different. Surgical cardiac replacement or repair procedures typically require more resources such as increased OR time, additional supportive staff for the procedure. The surgical procedures typically require cardiopulmonary bypass to accomplish the surgical valve replacement or repair and the recovery time,

including the length of stay is typically longer for the surgical procedures. As such, it is reasonable to expect that the resource utilization for the surgical procedures would be greater than those utilized for the endovascular repairs and as such, the current MS-DRG structure for MS-DRGS 266 and 267 should be maintained as proposed by CMS.

#### MS-DRG Logic for MS-DRG 215

*CMS received a request to review the GROUPER logic for MS-DRG 215 (Other Heart Assist System Implant) in MDC 05 (Diseases and Disorders of the Circulatory System) related to procedure codes describing the revision of malfunctioning devices within the heart via an open approach. After consideration, CMS proposed to maintain the GROUPER logic for MS-DRG 215 for FY 2025.*

STS agrees with CMS that, in general, most patients with indications for heart assist devices tend to be more severely ill and will require greater resource utilization than patient's that are admitted for open revision of devices related to heart valves, atrial septum, or ventricular septum. STS supports CMS' recommendation that the current GROUPER logic for MS-DRG 215 should be maintained for FY 2025.

#### **Changes to MS-DRG Diagnosis Codes (Major Complications and Comorbidities/Complications and Comorbidities)**

##### *Overview of Comprehensive CC/MCC Analysis*

*CMS proposes to finalize the list of nine principles established in FY 2021 for conducting its CC/MCC analysis. The nine guiding principles are as follows:*

- *Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.*
- *Denotes organ system instability or failure.*
- *Involves a chronic illness with susceptibility to exacerbations or abrupt decline.*
- *Serves as a marker for advanced disease states across multiple different comorbid conditions.*
- *Reflects systemic impact.*
- *Post-operative/post-procedure condition/complication impacting recovery.*
- *Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).*
- *Impedes patient cooperation or management of care or both.*
- *Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.*

STS supports CMS proposal to continue using mathematical analysis of claims data in combination with the nine guiding principles to determine the extent of the presence of secondary diagnosis codes reported increase hospital resource use. To encourage specificity related to the patient's health condition in the documentation allowing the capture and reporting of the most specific diagnosis codes. STS suggests that CMS provide facilities with feedback from the Medicare Code Editor (MCE) for each provider using "unspecified" diagnosis codes with designations as a CC or MCC when there are other codes available in that code subcategory that further specify the anatomic site. The facilities can then use this information to educate providers on the number of "unspecified" diagnosis codes being

reported compared to their peers and educate them on what documentation is required to in the documentation to report the more specific diagnosis codes available within the subcategory.

#### *Social Determinants of Health Diagnosis Codes*

*In FY 2023 rulemaking, CMS sought information on diagnosis codes that describe social determinants of health. Given the cited impact on health care needs, CMS proposes to re-designate ICD-10 diagnosis codes describing inadequate housing and housing instability from non-CC to CC and housing instability are non-CCs when they are reported as a secondary diagnosis.*

STS supports CMS' use of social determinants of health to better capture patient health. STS has a strong commitment to addressing social determinants of health and is particularly interested in the coverage of certain health-related social needs. Allowing for homelessness as a CC and housing instability as secondary diagnosis will encourage appropriate capture and documentation of these circumstances and ensure appropriate coverage for increased utilization associated with these circumstances.

#### **Add-On Payments for New Services and Technologies for FY 2025**

##### *Proposed FY 2025 Applications for New Technology Add-On Payments (Traditional Pathway)*

##### DuraGraft® (Vascular Conduit Solution)

*Marizyme, Inc. submitted an application for new technology add-on payments for DuraGraft® for FY 2025 (note the prior company, Somahlution, Inc., also submitted and withdrew applications in FY 2018 and FY 2019, and Marizyme, Inc., submitted and withdrew applications in FY 2020 and FY 2024). Per the applicant, DuraGraft® is an intraoperative vein-graft preservation solution used during the harvesting and grafting interval during coronary artery bypass graft surgery (CABG). CMS notes concerns regarding whether the technology meets the newness, cost and substantial clinical improvement criterion.*

STS remains concerned that the current data does not specifically support the newness or substantial clinical criterion at this time.

##### *Proposed FY 2025 Applications for New Technology Add-On Payments (Alternative Pathways)*

##### Edwards EVOQUETM Tricuspid Valve Replacement System (Transcatheter Tricuspid Valve Replacement System)

*Edwards Lifesciences LLC submitted an application for new technology add-on payments for the Edwards EVOQUETM Tricuspid Valve Replacement System ("EVOQUETM System") for FY 2025. According to the applicant, the EVOQUETM System is a new, transcatheter treatment option for patients with at least severe tricuspid regurgitation. CMS proposes to approve the EVOQUETM System for new technology add-on payments for FY 2025. Based on its existing policies, CMS proposes that the maximum new technology add-on payment for a case involving the use of the EVOQUETM System would be \$31,850 for FY 2025 (that is, 65% of the average cost of the technology).*

STS agrees with CMS that the EVOQUETM System qualifies under the new technology add-on payment under the alternative pathway criteria and that it meets the cost criterion. As such, STS supports CMS'

proposal to approve the EVOQUETM System for a NTAP at the maximum new technology add-on payment amount.

#### GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)

*W.L. Gore & Associates, Inc. submitted an application for new technology add-on payments for the TAMBE Device for FY 2025. Per the applicant, the TAMBE Device is used for endovascular repair in patients with thoracoabdominal aortic aneurysms (TAAA) and high-surgical risk patients with pararenal abdominal aortic aneurysms (PAAA) who have appropriate anatomy. CMS proposes to approve the TAMBE Device for new technology add-on payments for FY 2025. Based on its existing policies, CMS proposes that the maximum new technology add-on payment for a case involving the use of the TAMBE Device would be \$47,238.75 for FY 2025 (that is, 65% of the average cost of the technology).*

STS agrees with CMS that the TAMBE Device qualifies under the new technology add-on payment under the alternative pathway criteria and that it meets the cost criterion. As such, STS supports CMS' proposal to approve the TAMBE Device for a NTAP at the maximum new technology add-on payment amount.

#### TriClip™ G4

*Abbott submitted an application for new technology add-on payments for TriClip™ G4 for FY 2025. Per the applicant, TriClip™ G4 is intended for reconstruction of the insufficient tricuspid valve through tissue approximation via a transcatheter approach. CMS proposes to approve TriClip™ G4 for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024. Based on its existing policies, CMS proposes that the maximum new technology add-on payment for a case involving the use of TriClip™ G4 would be \$26,000 for FY 2025 (that is, 65% of the average cost of the technology).*

STS agrees with CMS that the TriClip™ G4 System qualifies under the new technology add-on payment under the alternative pathway criteria and that it meets the cost criterion. As such, STS supports CMS' proposal to approve the TriClip™ G4 System for a NTAP at the maximum new technology add-on payment amount subject to PMA approval of the Breakthrough Device indication before May 1, 2024.

#### **Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines**

*For cost reporting periods beginning on or after October 1, 2024, CMS proposes to establish a separate payment under the IPPS to small, independent hospitals for the additional resource costs involved in voluntarily establishing and maintaining access to 6-month buffer stocks of essential medicines, either directly or through contractual arrangements with a manufacturer, distributor, or intermediary. CMS proposes that the costs of buffer stocks that are eligible for separate payment are the costs of buffer stocks for one or more of the medicines on the Advanced Regenerative Manufacturing Institute's ARMI's List of 86 essential medicines.*

STS supports CMS' proposal to incentivize small, independent hospitals to maintain a 6-month buffer stock of essential medicines. This initiative is crucial for enhancing the resilience of healthcare providers and ensuring uninterrupted access to critical medications. However, we believe this program, once it has proven to be successful, should be expanded to include larger hospitals. Larger hospitals are not immune to supply chain disruptions, and their inability to access essential medicines can have cascading effects on the healthcare system. They also often serve as referral centers for smaller hospitals,



especially in complex cases requiring specialized care. Ensuring that all hospitals, regardless of size, maintain buffer stocks of essential medicines will create more robust and uniform preparedness across sites.

### **Transforming Episode Accountability Model (TEAM)**

#### **General Provisions**

*CMS proposes to implement a mandatory model, TEAM, using its authority under section 1115A of the Act. The TEAM builds on and incorporates what the agency deems the most promising model features from other Center for Medicare and Medicaid Innovation (Innovation Center) episode-based payment models such as the Bundled Payments for Care (BPCI) Advanced Model and the Comprehensive Joint Replacement (CJR) Model.*

*Under the TEAM, selected acute care hospitals in certain geographic areas would be required to participate and be accountable for five initial episode categories:*

- *coronary artery bypass graft,*
- *lower extremity joint replacement,*
- *major bowel procedure,*
- *surgical hip/femur fracture treatment (excluding lower extremity joint replacement), and*
- *spinal fusion.*

STS appreciates that the Innovation Center continues to develop new alternative payment models (APMs) that aim to align financial incentives while improving care coordination. We also appreciate that the Innovation Center is focusing on developing payment models for specialty medicine, where limited APM options under the Quality Payment Program (QPP) exist (i.e., Advanced APMs). STS is eager to move reimbursement methodologies towards value-based payment models, which, when appropriately implemented, can help to improve care delivery for our patients. Through our quality measurement, public reporting, and other quality improvement initiatives using the STS National Database, we remain on the forefront of quality assessment and improvement. We continue to seek opportunities to work with the administration to share our expertise and ideas on how to build a payment model that truly recognizes healthcare quality.

We do, however, have concerns about how the TEAM is being implemented and whether CMS will be successful in reducing costs while improving quality and care coordination. Throughout the TEAM proposal, CMS refers to policies incorporated from previous models like BPCI Advanced and CJR. In the proposed rule, CMS details that evaluation of these models is still on-going, and the results of these models based on their current methodologies will not be available until after they have concluded. BPCI Advanced is set to conclude on December 31, 2025, while the TEAM is scheduled to begin on January 1, 2026, leaving no time for lessons learned from BPCI Advanced to be incorporated into this new model from which the TEAM is heavily influenced. Current data captured on BPCI Advanced and CJR show that there were no Medicare savings generated, statistically insignificant Medicare savings, or significant Medicare losses. In a study of 694 participating and 2,852 nonparticipating hospitals between 2013 and

2019, BPCI Advanced was associated with a \$279.2 million net increase in Medicare spending.<sup>1</sup> Additionally, participation in BPCI Advanced was not associated with changes in care utilization or quality improvements for the cardiovascular medical events or procedures offered in the model.<sup>2</sup>

In the first performance year of BPCI Advanced (2018-2019), 22% of eligible hospitals and 23% of eligible clinicians participated in the program, which paid for 16% of potential episodes. While these adoption rates were higher than the previous iterations of BPCI, most hospitals that expressed interest did not ultimately enroll. Hospitals that did enroll in BPCI Advanced were more likely to be urban, larger, and non-profit. Therefore, to the extent there are improvements in quality or efficiency, patients in rural areas with smaller health systems may be left behind.<sup>3</sup> Without a proven track record of model success, STS is extremely concerned about the proposal to mandate participation in TEAM for hospitals in selected geographic areas. Not only could this lead to unwarranted penalties for participants, the disruption in reimbursements could threaten to de-stabilize the delivery of critical health care services such as CABG and related post-operative care.

## **Participants**

### *Proposed TEAM Participant Definition*

*To avoid complexities in the TEAM, CMS proposes that the acute care hospital TEAM participant will be the only entity eligible to initiate an episode. More specifically, CMS proposes to define “TEAM participant” as an acute care hospital that initiates episodes and is paid under the IPPS with a CMS Certification Number (CCN) primary address located in one of the geographic areas selected for participation in TEAM.*

Because patient-centered care is team based, STS is appreciative of CMS’ decision to define a TEAM participant as an acute care hospital instead of putting the onus on individual physicians. However, we have seen in the example of hospital-led Accountable Care Organizations (ACOs) that the participant hospitals must balance conflicting incentives. The savings gained from reducing hospitalizations are offset by the loss of admission revenues. Consequently, these ACOs have shifted their focus to cutting post-acute care costs. Although models targeting high-cost groups, such as patients with end-stage renal disease, have produced the most significant savings, some evidence points to risk selection and regression to the mean as underlying factors.<sup>4</sup>

With few exceptions, value-based payment has yet to enhance—or even specifically address—access to care or health outcomes for populations with social risk factors, including racial and ethnic minorities,

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<sup>1</sup> Shashikumar, Sukruth A et al. “Association of Hospital Participation in Bundled Payments for Care Improvement Advanced With Medicare Spending and Hospital Incentive Payments.” *JAMA* vol. 328,16 (2022): 1616-1623. doi:10.1001/jama.2022.18529

<sup>2</sup> Shashikumar SA, Zheng J, Orav EJ, Epstein AM, Joynt Maddox KE. Changes in Cardiovascular Spending, Care Utilization, and Clinical Outcomes Associated With Participation in Bundled Payments for Care Improvement - Advanced. *Circulation*. 2023 Oct 3;148(14):1074-1083. doi: 10.1161/CIRCULATIONAHA.123.065109. Epub 2023 Sep 8. PMID: 37681315; PMCID: PMC10540757.

<sup>3</sup> <https://ldi.upenn.edu/our-work/research-updates/the-future-of-value-based-payment-a-road-map-to-2030/>

<sup>4</sup> <https://ldi.upenn.edu/our-work/research-updates/the-future-of-value-based-payment-a-road-map-to-2030/>

rural communities, and individuals with disabilities.<sup>5</sup> We caution CMS to ensure that the models mandated for hospital participation are tested and proven to have effectively balanced cost savings with quality improvement.

### **Proposed Mandatory Participation**

*CMS proposes making the TEAM a mandatory model for those hospitals in the geographic areas that are selected for the model. While aspects of the TEAM are based on previously existing APMs, CMS notes that the mandatory participation requirement is not limited to hospitals that have participated in those previous models.*

*CMS proposes that there will be no “voluntary opt-in” option out of concern for selection bias. However, CMS seeks comment on whether it should create a “voluntary opt-in” performance option for hospitals that currently participate in BPCI Advanced or the CJR model (if not located in a geographic area that would require participation under the TEAM).*

STS cautions against CMS’ urgency to operationalize the TEAM as we feel the application and implementation process is too aggressive. TEAM is a new and untested model. While pieces of the model have been lifted from established models, combining the pieces together as proposed in TEAM should be treated as an experimental model and made voluntary. Further, it would be premature to make this model mandatory when its predecessors BPCI Advanced and CJR have yet to show positive outcomes, and CMS has admitted that more time is needed to evaluate their effectiveness.

Based on the insights we have learned from BPCI Advanced so far, a voluntary track is especially necessary for smaller, rural, and safety-net hospitals that have not previously participated in APMs and may not have the resources necessary for successful participation. In a study of 832 hospitals that participated in BPCI Advanced, participants were more often large, urban teaching hospitals with higher operating margins and lower proportions of dually enrolled beneficiaries (i.e., Medicare and Medicaid dual enrollees). Conversely, among initial BPCI Advanced participants, 123 (14.8%) dropped out of inpatient bundles fully and 371 (44.6%) dropped at least 1 bundle. These hospitals were more often for profit, smaller, and located in areas with a lower supply of skilled nursing and inpatient rehabilitation facilities.<sup>6</sup>

We have also learned from CJR that mandatory participation does not equate to Medicare savings. Mandatory CJR hospitals generated an estimated \$23.4 million in losses during the first 5 performance years. The 90% confidence interval for the estimated losses ranges from losses of \$155.2 million to savings of \$108.4 million. This equates to losses of \$114 per episode, ranging from losses of \$754 to savings of \$527, or approximately 0.4% of the baseline average episode payment.<sup>7</sup>

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<sup>5</sup> [https://ldi.upenn.edu/wp-content/uploads/2021/07/PennLDI-Future-of-Value-Based-Payment-WhitePaper.pdf?\\_ga=2.53978600.1784586575.1693339128-1626887975.1693339128](https://ldi.upenn.edu/wp-content/uploads/2021/07/PennLDI-Future-of-Value-Based-Payment-WhitePaper.pdf?_ga=2.53978600.1784586575.1693339128-1626887975.1693339128)

<sup>6</sup> Joynt Maddox KE, Orav EJ, Zheng J, Epstein AM. Characteristics of Hospitals That Did and Did Not Join the Bundled Payments for Care Improvement–Advanced Program. *JAMA*. 2019;322(4):362–364. doi:10.1001/jama.2019.7992

<sup>7</sup> <https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report>

While we recognize this may present issues for CMMI as they evaluate the model design, we suggest they use other incentives for participation rather than imposing this burden on facilities that are already overburdened with Medicare reporting programs.

### **Episode Length**

*CMS proposes that episodes end 30 days after discharge from the anchor hospitalization or anchor procedure and that day 1 of the 30-day post-acute portion of the episode is the date of the anchor procedure or the date of discharge from an anchor hospitalization.*

*CMS proposes that episodes end 30 days after discharge from the anchor hospitalization or anchor procedure and that day 1 of the 30-day post-acute portion of the episode is the date of the anchor procedure or the date of discharge from an anchor hospitalization. A 30-day episode also would position the specialist as the principal provider near the anchor event with a hand off back to the primary care provider for longitudinal care management.*

STS encourages CMS to reconsider the proposed 30-day episode length. We believe that 30-day episodes are too short for participants to effectively identify high-risk patients. Due to data lag in claims-based models, 30-day episodes would end before participants receive data on post-acute care. This short period limits the actionable costs included and the participant's ability to identify and address improvement opportunities.

Instead, CMS should keep the 90-day episode structure that has proven effective in the CJR and BPCI Advanced models. These models, grounded in academic research and real-world testing, support maintaining the current 90-day period which offers significant advantages for CMS, providers, and most importantly, patients. By capturing the comprehensive 90-day period, CMS can access the full scope of a beneficiary's care, enabling robust evaluation and continuity with prior models. This data helps CMS determine the optimal episode length for each clinical condition, which would be challenging with only 30 days of claims data. Providers will have sufficient time to manage follow-up care before transferring responsibilities. For example, most major surgeries require about six weeks for recovery, which means a 30-day period would miss critical post-acute care to prevent complications. Lastly, patients would benefit from extended coordinated care. As CMS has stated, if the goal of the TEAM is to improve care coordination, then it is important that they track care coordination outside of the proposed 30-day period.

Keeping the 90-day episode length also helps participants meet financial targets. All potentially actionable costs occur after the initial admission or procedure. To achieve the target, including the CMS discount, participants need to reduce post-acute care spending. If the episode length is cut to 30 days, all cost savings must happen within that period. For example, in BPCI Advanced episodes, over half of post-acute spending typically occurs between days 31-90. Therefore, a 30-day episode would require participants to double their savings within that reduced timeframe to meet targets. To provide participants the opportunity to design care delivery improvements and efficiencies, it is imperative that the model provide participants the space to focus on areas for improvement that are specific to that facility. To cut off a facility's access to demonstrating savings in days 31 to 90 will, for some facilities, doom them to penalties if they otherwise have a track record of efficiency in days 0 – 30.

### **Quality Measures and Reporting**

## *Selection of Proposed Quality Measures*

*CMS proposes that TEAM would incorporate quality measures that focus on care coordination, patient safety, and patient reported outcomes (PROs), which CMS believes represents areas of quality that are particularly important to patients undergoing acute procedures. Wherever possible, CMS would align TEAM quality measures with those used in ongoing models and programs to minimize participant burden.*

*CMS proposes the following quality measures, which are described in more detail in the sections that follow:*

- For all TEAM episodes: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356);*
- For all TEAM episodes: CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135); and*
- For Lower Extremity Joint Replacement (LEJR) episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618)*

STS believes that data collection and the pursuit of quality improvement is necessary for all value-based payment models. Identifying appropriate quality measures is a vital component of the success of the TEAM. STS is unclear exactly what CMS is attempting to capture with these general measures that provide little information on CABG performance. While we appreciate CMS' efforts to streamline data collection for quality improvement by choosing measures that are already in effect in other programs, we do not feel the measures proposed are an appropriate benchmark for quality.

Instead, STS encourages CMS to utilize specialty specific measures that would better capture performance on the episodes proposed. Similar to the goals of TEAM, the BPCI Advanced model aims to promote seamless, patient-centered care throughout each clinical episode, regardless of who is responsible for a specific element of that care. Through the evolutions of BPCI Advanced, CMS determined that providers require a better indicator of the quality of CABG procedures than was provided through general surgical measures to account for differences in care that could lead to poor outcomes. The CMS Innovation Center added the CABG Composite Score (CMIT ID #1737) measure to the BPCI Advanced Model to provide a more complete reflection of care provided. STS urges CMS to reconsider the use of generic measures in the CABG episodes and to use the CABG Composite Score measure to better reflect care in the CABG episode.

The STS National Database™, Adult Cardiac Surgery Database (ACSD) registry has worked with leaders in the field to develop, test and implement the CABG Composite Score measure. The Society has a long history of rigorous real-world clinical data collection and quality improvement through the STS National Database and its component registries. Additionally, the ACSD is the largest cardiac surgical database in the world and includes information regarding over 9 million adult cardiac surgical operations.<sup>8</sup> For these reasons, we are uniquely qualified to determine the best methodology for measuring CABG procedures

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<sup>8</sup> Wylter von Ballmoos, M. C., Kaneko, T., Iribarne, A., Kim, K. M., Arghami, A., Fiedler, A., Habib, R., Parsons, N., Elhalabi, Z., Krohn, C., & Bowdish, M. E. (2024). The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2023 Update on Procedure Data and Research. *The Annals of thoracic surgery*, 117(2), 260–270. <https://doi.org/10.1016/j.athoracsur.2023.11.016>

and have extensive data to support our recommendations. CMS should utilize STS as resource for data collection and scoring of measures related to CABG. It is difficult for STS to believe that CMS can attest to the quality and outcomes of patients receiving CABG on only an all-cause readmission measure and a patient safety and adverse events composite measure. It is unclear how CMS can use these measures to truly evaluate whether the model has improved care for patients who have undergone a CABG.

## **Pricing and Payment Methodology**

### *Discount Factor*

*CMS proposes to apply a 3% discount factor to the benchmark price to serve as Medicare's portion of reduced expenditures from the episode. CMS also discusses and seeks feedback on alternatives for applying discount factors or including different discount factors based on episode category or different types of TEAM participants.*

As mentioned above, STS has significant concerns about the potential “race to the bottom” impact that this model may have, and we feel that is tied directly to the proposed 3% discount factor. While we appreciate CMS’ efforts to lessen this ratcheting effect by using a 3-year baseline period and rebasing annually, we are doubtful this proposal will mitigate the issue of compounding discounts. We have learned from previous models that continued adherence to decreasing target prices year after year is unsustainable for practices. Rothman Orthopedics, the largest orthopedic group in the country, have spoken publicly about having to drop out of CJR and other value-based care agreements due to compounding cuts for cost savings.<sup>9</sup> Hospitals that prove to be successful in the TEAM will cut spending, and spending targets could be further reduced based on lower total cost of care for future years, limiting longer-term opportunities for success in value-based care.<sup>10</sup>

More specifically, STS has concerns over how the proposed 3% discount factor will materialize for CABG episodes. Data from the BPCI Advanced model showed that in the CABG episode, the MS-DRG and minimal professional fees make up almost 80% of associated costs. The only actionable area for cutting costs is within post-acute care, which accounts for 22% of spending. Since savings will need to occur within the post-acute care window, in order to meet the 3% net discount factor, hospitals will need to reduce spending by 14%. Compared to the other episodes like lower extremity joint replacement (40% post-acute care spending) and surgical hip/femur fracture (63% post-acute care spending), CABG episodes will need to have the highest reduction in spending during this window due to the fixed DRG cost. This would be a drastic cut to spending in the post-acute care window and hospitals will struggle to balance cost savings with maintained or improved quality and patient care.

Further, STS is supportive of models incorporating a method to account for the investment and infrastructure start-up costs associated with transitioning to an APM. CMS fails to appropriately and broadly account for these investment resources needed to redesign care delivery to align with the

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<sup>9</sup> <https://www.hmpgloballearningnetwork.com/site/pophealth/population-points/population-health-and-cms-policies-race-bottom>

<sup>10</sup> <https://www.sg2.com/health-care-intelligence-blog/2022/10/value-based-care-economics-are-more-compatible-with-fee-for-service-models-than-you-realize/#:~:text=Adding%20to%20the%20discomfort%20are,tar%20could%20be%20reduced%20based>

incentives of a model (except for perhaps considering infrastructure payments for safety net hospitals). STS believes CMS should eliminate the discount factor as part of the reconciliation. This would allow participants more flexibility to garner the resources needed at the outset of the transition to this model. This would be a particularly important change in the context of a mandatory model.

### *Risk Adjustment and Normalization*

*CMS discusses its proposals for risk adjustment and normalization which are based on the risk adjustment for the CJR extension, with a few key differences. Proposals include:*

- *To calculate risk adjustment coefficients at the MS-DRG/Healthcare Common Procedure Coding System (HCPCS) episode type level*
- *To use the same age bracket risk adjustment variables (less than 65 years, 65 years to less than 75 years, 75 to less than 85 years, and 85 years or more) based on the participant's age on the first day of the episode, as determined through Medicare enrollment data*
- *To use a hierarchical condition count (HCC) risk adjustment variable that would look at the beneficiary's Medicare FFS claims from a 90-day lookback period (beginning with the day prior to the anchor hospitalization or procedure) to determine which HCC flags to include in the count*
- *To use a risk adjustment variable that accounts for potential markers of beneficiary social risk. The variable would be "yes" if one or more of the following apply: full Medicare/Medicaid dual eligibility status, being in a state or national Area Deprivation Index percentile beyond a certain threshold (80th percentile for the national ADI and 8th decile for the state ADI), or Medicare Part D Low Income Subsidy. CMS would only adjust target prices if the coefficient on the beneficiary social risk adjustment variable is positive.*
- *To incorporate a prospective normalization factor into preliminary target prices, which would be subject to a limited adjustment at reconciliation based on the observed case mix, up to +/- 5%.*

While STS appreciates CMS' goal of balancing simplicity with accuracy, we feel the current risk-adjustment methodology is lacking as proposed. Without proper risk-adjustment, STS has significant concerns that patient population could drastically impact a hospital's success. We fear it could negatively impact specialists' ability to treat comorbid or higher-risk patients and that hospital administrators may influence primary care providers to avoid surgical procedures. For example, a diabetic patient may be referred to an interventional cardiologist to receive a percutaneous coronary intervention (PCI) and then sent to another hospital for follow-up care to avoid a high-cost CABG that would have been the preferable intervention.

Additionally, as we've noted above, medical episodes may also be more difficult to manage for rural or safety-net hospitals and hospitals without previous experience implementing value-based care. For these reasons, we feel that CMS should use the BPCI Advanced methodology which uses more complex risk adjustment and more risk adjustment coefficients, including both patient and provider characteristics. As CMS detailed, categories of patient characteristics include (but are not limited to): HCCs (individual flags, interactions, and counts), recent resource use, and demographics. Provider characteristics, which are used to group hospitals into peer groups, include bed size, rural vs. urban, safety net vs. non-safety net, and whether or not the participant is a major teaching hospital. We do

caution that when using the TEAM HCC Count that would rely on a 90-day look back period for each beneficiary beginning the day prior to the anchor hospitalization/procedure, CMS needs to also account for conditions/other procedures that might initiate during the episode itself. This would be especially necessary if CMS were to adopt the 90-day episode as we recommend.

Risk methodology for payment should also include clinical data and the STS Risk Models (already utilized by CMS in other settings) can be a useful addition to the coefficients in the BPCI Advanced model. Risk adjustment using clinical data has proven to be reliable and accurate. STS has developed robust, highly credible risk adjustment models for mortality and morbidity as clinical outcomes, but risk adjustment models for resource utilization are much less well developed. For example, clinical factors that are key to risk-adjustment cannot be ascertained using a 90-day lookback period using fee-for-service claims, meaning the HCC count approach proposed may not give adequate results. The STS Risk models do not have this limitation and will likely provide more reliable risk-adjustment. It is for this reason that access to Medicare claims data that are then combined with STS clinical data are so crucial for developing credible and statistically valid prospective payment systems that take into account the clinical variables that have a dominant effect on resource use. Unfortunately, claims data alone have been demonstrated to have major flaws, but the combination of clinical and resource data will yield a much more valid and credible model for predicting resource use. We urge CMS to use the best possible tools available to provide accurate risk adjustment for this program to ensure there are no disruptions in access to care for participating hospitals. Use of the STS database as a tool to define clinical risk corridors that define financial risk would be the most appropriate tool for patient safety. We recommend using the STS Risk Models which are highly calibrated, based on granular clinical datasets and include many of the characteristics outlined in the TEAM and BPCI Advanced risk adjustment models. Without this tool, high-risk Medicare beneficiaries will certainly be disenfranchised from the medical care that they so desperately need.

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Associate Director of Health Policy, at [mpeltzman@sts.org](mailto:mpeltzman@sts.org) or Derek Brandt, Vice President of Government Relations at [dbrandt@sts.org](mailto:dbrandt@sts.org) should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer C. Romano". The signature is fluid and cursive, with the first name being the most prominent.

Jennifer C. Romano, MD  
President