



The Society of Thoracic Surgeons

STS Headquarters

633 N Saint Clair St, Floor 23
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org

STS Washington Office

20 F St NW, Ste 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacy@sts.org

www.sts.org

June 20, 2016

Lew Sandy, MD
Chair of the Clinical Episode Payment Work Group
Health Care Payment Learning & Action Network
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

**Re: Accelerating and Aligning Clinical Episode Payment Models:
Coronary Artery Disease Draft White Paper**

Dear Dr. Sandy:

On behalf of The Society of Thoracic Surgeons (STS) I write to submit comments on the Health Care Payment Learning & Action Network draft white paper on Accelerating and Aligning Clinical Episode Payment Models: Coronary Artery Disease. Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy. We appreciate the opportunity to comment on this draft whitepaper.

In general, we appreciate the panel's efforts to design a model that prioritizes helping providers to coordinate patient care for coronary artery disease (CAD). As the whitepaper states, CAD is one of the principal cost centers in all of medicine and this patient population stands to benefit from concerted efforts to coordinate and improve quality and efficiencies in care. We agree with the assessment that care coordination for patients with CAD should consider the entire patient experience, not just a single procedural intervention or an acute episode. We also appreciate the challenges of defining a patient condition-level payment period and integrating shared decision-making episode-based payment for a specific intervention (Percutaneous Coronary Intervention (PCI), or Coronary Artery Bypass Graft (CABG)). We also agree that the model should focus on identifying CAD patients earlier – either upon acute/subacute diagnosis, or upon findings on exam, stress test or echo for annual physical – so that they can be medically managed. This early detection will give the providers in the patient's "heart team" (a concept to be explained later in this document) more time to agree upon a recommendation for the appropriate intervention at the appropriate time. However, as the panel has discovered, this goal is a very high bar to attain.

We encourage the panel to revisit the proposal from the perspective of the patients, providers, and hospital administrators in order to practically

understand the impact of such a model on care delivery. Although the whitepaper acknowledges concerns likely to be articulated by various stakeholders, those stakeholders were noticeably absent from the writing panel. The Society is in the process of applying to become a Committed Partner in the Health Care Payment and Learning Action Network (HCP-LAN) and we would appreciate the opportunity to be more formally involved with the revision and finalization of this proposal.

We are primarily concerned that the treatment of patients with CAD is not likely to fit neatly into a 12-month period beginning the first of each year. Patients who are previously undiagnosed with CAD prior to presenting with an acute event (either ST elevation myocardial infarction (MI) or non-ST elevation MI) may have PCI and/or CABG upon presentation or shortly thereafter, making it possible that majority of the CAD care provided to them would fall outside the condition episode. Furthermore, requiring all patients to enter the condition episode on a scheduled, annual basis could be overwhelming, at the very least in high volume centers.

The fluidity of the model as proposed would lend itself to a wide variety of patient experiences and a number of uncontrolled variables. One patient may have months of medical management before a specific intervention (PCI or CABG) is performed while another could enter the bundle days or hours before the procedure. The whitepaper does not discuss the impact this disparity will have on the patient experience pre- and post-procedure and therefore raises a number of questions: could post-operative care be discontinued prematurely if the intervention occurs late in the condition period? Will patients be encouraged to have procedures before they need them to fit into the prescribed period? Can a patient trigger a subsequent CAD payment bundle once the term of the first has expired?

What follows is an analysis of some specific portions of the proposal from the surgeon's perspective. We hope to have the opportunity to ensure that this perspective is represented throughout the whitepaper:

Data Access

We appreciate that the authors recognized the value of the STS National Database, which was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. The fundamental principle underlying the STS National Database initiative has been that surgeon engagement in the process of collecting information on every case, combined with robust risk adjustment based on pooled national data, and feedback of the risk-adjusted data provided to the individual practice and the institution, will provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients.

We encourage the private payors who are HCP-LAN Committed Partners to join us in our quest to capture all relevant (de-identified) patient data. With robust clinical information, combined with cost information from all payors, we can increase our understanding of the CAD condition episode and improve the quality and efficiency of the nested procedural bundle. We believe that

as members of a profession with a responsibility to wisely allocate societal healthcare resources, resource utilization is an outcome that deserves our focus and attention in the same way that we focus on mortality rates, wound infections, and other clinical outcomes. The white paper acknowledges that access to pricing information is important in the implementation of the model. We must give providers the tools to not only understand the cost of the procedures they perform but also the drivers of cost within a condition episode.

The STS National Database has facilitated advancements in many aspects of health care policy, including public reporting of health care quality measures, facilitating medical technology approval and coverage decisions, and even saving money by helping cardiothoracic surgeons to find the most efficient and effective way to treat patients. Clinical data from the STS National Database has been linked with administrative claims data from CMS on a number of occasions, as a part of specific research requests to the Research Data Assistance Center (ResDAC), and through our data warehouse at the Duke Clinical Research Institute (DCRI). There are also regional examples of combining STS National Database data with claims information, most notably, the Virginia Cardiac Surgery Quality Initiative (VCSQI). These discrete instances have demonstrated important new ways to assess the effectiveness of treatment options and offered new avenues for medical research. Clinical data yield sophisticated risk adjustment assessments, while administrative data provide information on costs as well as long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, and medication use. Since “value=quality/cost,” the combination of these clinical and resource use data sets will yield powerful information that can be used by providers to achieve the goal of increasing the value of healthcare that is delivered in the cardiovascular domain.

We are very disappointed with CMS’s decision not to adopt new policies or procedures to implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). Section 105(b) requires CMS to provide “qualified clinical data registries” (QCDRs) with access to Medicare data for purposes of linking such data with clinical outcomes data and performing scientifically valid analysis or research to support quality improvement or patient safety. Providing QCDRs with regular and timely access to Medicare claims data is critical to the future of Medicare payment policy, which is now inextricably linked to quality improvement and resource use. It will also dramatically increase the power of clinical outcomes data collected by QCDRs and therefore yield immeasurable benefits for patient health and safety. Although access does exist in the ResDAC process, a data user agreement must be requested each time a new time frame is established for measurement. This additional administrative step greatly prohibits timely access to financial data to which providers can respond. We have also encouraged CMS to match Medicare claims data with Social Security Death Masterfile (SSDMF) death data before providing it to QCDRs to further enhance the accuracy and robustness the Medicare claims data. Patient outcomes information derived from the seamless combination of these data sources creates a powerful tool for tracking patient outcomes and resource use over an extended period of time. The implications of such longitudinal studies for quality improvement and value enhancement are dramatic.

Appropriateness Criteria and the Heart Team

We agree that a goal of the CAD clinical episode payment model should be to identify and medically manage CAD patients earlier so that acute episodes and interventions can be avoided if possible. This will also allow for better assessment and decision-making around the types of procedures that are performed. Surgeons are a critical part of that decision-making process, yet, in this proposal their role seems to be de-emphasized and relegated to providing a service at the direction of the accountable entity (the primary care provider (PCP) or the cardiologist), based on his/her willingness to refer patients. Further, since the model is designed to assess and improve long-term patient outcomes and decrease overall costs, the model must take into account longitudinal data to facilitate these decisions. Our experience has shown that when you change the goal to making sure patients are healthier in the long-term different types of interventions may be preferable. The whitepaper seems to imply that consultation of appropriate use criteria (AUC) and clinical practice guidelines fulfill this mission. We encourage the panel to go beyond the adoption of AUC and guidelines and utilize (and pay for) a *heart team* consultation whenever possible. This heart team approach was federally mandated for transcatheter aortic valve replacement programs and has been successfully applied to coronary artery disease management in many institutions. Under this approach, once a physician has determined a patient may need revascularization or treatment for CAD, the physician would refer the beneficiary to a team of professionals dedicated to understanding revascularization – a heart team – which would review all pertinent data, see the patient and family in consultation, and recommend the appropriate intervention and/or treatment for that individual. Payors should reimburse each of the members of the heart team for their role in assessing the case and contributing to a process which results in a treatment recommendation for the patient. The team would include cardiothoracic surgeons, cardiologists, cardiac anesthesiologists and hospitalists.

Prospective / Retrospective Payment

The Society agrees that, at least at the outset, the retrospective reconciliation approach to bundled payment is the only feasible way to proceed. However, our members' experiences with similar payment models have yielded a number of valuable lessons and concerns with this approach:

- Patient identification processes must be appropriate for the model;
- The model must have the ability to track the patient's clinical outcome during the episode of care and directly link the outcomes with predetermined clinical and financial metrics appropriate for such care;
- Participants must have fiscal software that will be able to accurately track and account for costs of care delivery;
- Information technology that will allow expeditious reconciliation of the patient's bills and interim costs during both procedural and medical care delivery must be utilized;
- There must be ongoing and "real-time" oversight of the model and the ability to modify such models as experience is generated and knowledge is gained that will positively or negatively impact both the financial and clinical components of the model current risk-adjustment models for clinical outcomes will likely differ in important ways from risk-adjustment models where resource utilization is the outcome); and

- The governance structure must include representation by all payors, patients, and providers that will enhance communication and coordination for improvement in delivery and documentation.

We also think that the process for distributing savings or costs under the model needs to be better explained. Hospitals will be a key player in this payment scheme, yet they are entirely missing from the whitepaper discussion. The question of who gets the check and how it will be divided among the various participants in the model is a critical question that must be addressed.

In addition, the discussion of the “price” of the episodes does not reference the relative value of the services contained in the bundle despite the panel’s acknowledgement that the model must rely on a fee-for-service infrastructure. We encourage the panel to rely on the existing relative value scale until such time as the condition and episode based bundles can be clearly defined and valued as independent entities (relative to the rest of medicine). This will require all-payor analysis of both regional and specialty specific data to provide a basis for decision making and benchmarking prior to any and all initiation of a project. Furthermore, it may well be appropriate to pilot such models. VCSQI is an example of how such a model, based on the current 90-day global payment period, has already been operationalized. In existence since 1993, the VCSQI currently has amassed a database by combining the STS National Cardiac Database for Virginia with the patient’s UB-04 financial record for over 100,000 patients undergoing cardiac surgery in this region. This database therefore combines the patient’s clinical outcome with their financial cost record for over 98% of all patients undergoing cardiac surgery in Virginia. Evidence-based protocols for treatment of post-operative atrial fibrillation, transfusion reduction in cardiac surgery, early extubation following open heart surgical procedures, and glucose management have saved approximately \$90 million dollars in reduction of post-operative mortality and morbidity in cardiac surgery. Such an organization and ability to track and measure outcomes would be readily able to pilot models of alternative payment methodology.

Quality Measurement / Risk Adjustment / Public Reporting

We appreciate that the panel recognized the value of the STS National Database. We encourage the panel to rely on the Database as a source for quality measurement, risk adjustment, and public reporting. Although the paper makes reference to this resource, we have described it below to highlight its value within the context of this model.

Quality

The model described in the whitepaper makes passive reference to overall quality of patient care, quality measurement, and reporting. STS believes that the best measures of physician performance are generated by physicians using robust clinical information. STS has sponsored more NQF-endorsed quality measures (34) than any other professional organization, and these include risk-adjusted morbidity and mortality measures that have already driven change and improvements in care for Medicare beneficiaries. Many of the economic pressures described above that could inadvertently incentivize decision-making that is not in the patient’s best interest can, and should be addressed by superimposing a pay-for-quality infrastructure over the proposed condition and procedure episode(s). Previous studies support the premise that the use

of evidence-based team care can avoid unnecessary testing and inappropriate or futile therapy.¹² In addition, the identification and reduction of high cost postoperative complications can substantially improve quality and reduce spending.³⁴⁵⁶

STS aims to blend the STS ND and claims information from Medicare and other payors to create a clinical/financial tool to track patient outcomes relative to costs, while identifying high frequency and/or costly complications. The blended database would be used to develop best practice protocols aimed at reducing health care costs by minimizing complications and/or cutting excess resource utilization while maintaining quality. VCSQI has already created such a tool with demonstrated success. Future iterations of this tool may also be linked with the American College of Cardiology's National Cardiovascular Data Registry (NCDR®) to facilitate a longitudinal, population management payment model. In addition to maintaining robust quality reporting to better inform patient decision-making and provider referrals, participants in the STS model would be given the opportunity to select from a menu of quality improvement initiatives designed to target key areas for improvement in quality and efficiency.

Risk Adjustment

As the whitepaper suggests, risk-adjustment is essential to the success of the new CAD model. The STS National Database, which has more than 5.4 million patient records, has long used risk adjustment to provide more accurate patient clinical outcomes. To accurately measure cardiac surgery outcomes, it is critical to adjust the results for each surgeon and hospital by accounting for the severity of their patients' illnesses. To level the playing field, statistical techniques have been developed to account for the condition of patients before surgery. This has resulted in one of the most commonly reported measures of cardiac surgery quality, the risk-adjusted or risk-standardized mortality rate. STS has developed risk models for CABG, valve, and combined valve and CABG operations that have all received national recognition and endorsement.

The STS Risk Calculator (available to the public here: <http://www.sts.org/quality-research-patient-safety/quality/risk-calculator-and-models/risk-calculator>) allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

¹ Alan M. Speir, MD, Vigneshwar Kasirajan, MD, Scott D. Barnett, PhD, and Edwin Fonner, Jr, DrPH, Additive Costs of Postoperative Complications for Isolated Coronary Artery Bypass Grafting Patients in Virginia, *Ann Thorac Surg* 2009;88:40-6

² Ruben L. Osnabrugge, MS, Alan M. Speir, MD, Stuart J. Head, PhD, Philip G. Jones, MS, Gorav Ailawadi, MD, Clifford E. Fonner, MA, Edwin Fonner, Jr, DrPH, A. Pieter Kappetein, MD, PhD, and Jeffrey B. Rich, MD, Prediction of Costs and Length of Stay in Coronary Artery Bypass Grafting, *Ann Thorac Surg* 2014;98:1286-93

³ Osnabrugge, MSc, Ruben L, et al. "Cost, quality, and value in coronary artery bypass grafting." *The Journal of Thoracic and Cardiovascular Surgery*, 2014: 2729-2735.e1.

⁴ LaPar, MD, MSc., Damien J., et al. "Preoperative renal function predicts hospital costs and length of stay in coronary artery bypass grafting." *The Annals of Thoracic Surgery*, 2016: 606-612.

⁵ LaPar, MD, MS, Damien J., et al. "Postoperative atrial fibrillation significantly increases mortality, hospital readmission, and hospital costs." *The Annals of Thoracic Surgery*, 2014: 527-533

⁶ Holmes, Jr. MD, David R., Jeffrey B. Rich, MD, William A. Zoghbi, MD, and Michael J. Mack, MD. "The Heart Team of Cardiovascular Care." *The Journal of the American College of Cardiology*, 2013: 903-907.

There is now an increasing recognition nationally that performance measurement must be more comprehensive than just single procedures and outcomes. For example, consider two patients who survive CABG surgery. One has a perfectly uncomplicated course and receives all the appropriate treatments postoperatively, whereas the other patient develops kidney failure or a serious wound infection. Although both patients are survivors, their quality of care may have been very different. Because of such considerations, many organizations have recommended the use of multiple measures of quality for specific conditions and procedures, sometimes combining them into one number called a composite score. The composite score is a single number or rating that summarizes all available information about the quality of care delivered by an individual provider. It is this principle that led The Society of Thoracic Surgeons to develop what is known as the STS CABG composite score and rating, now one of the most sophisticated and widely regarded overall measures of quality in health care. Subsequently the STS AVR composite score and most recently the STS AVR+CABG composite score were developed due to the success of its CABG predecessor, and further composite measures for other procedures are currently being developed.

Public Reporting

Public reporting is no longer an “emerging trend” but rather a routine expectation of patients, payers, legislators and health care policy makers. In addition to adopting a heart team approach to CAD patient management, public reporting will be an essential tool in helping the accountable entity to manage appropriate referrals. STS leadership believes that the public has a right to see and understand the quality of surgical outcomes, and regards public reporting as an ethical responsibility of the specialty. STS volunteer leaders have worked diligently to develop a mechanism whereby Database participants can voluntarily report their STS isolated coronary artery bypass grafting (CABG) and isolated aortic valve replacement (AVR) composite star ratings (overall and component domains).

STS has long recognized the importance of taking a leadership role in developing fair and meaningful reporting structures. Evaluations of quality based solely on administrative or claims data is incomplete in the best case scenario, and potentially inaccurate and misleading in the worst. STS methodology for the CABG composite uses more accurate clinical data and includes 11 individual components of clinical care, including mortality and morbidity rates and adherence to NQF-endorsed measures of quality.

STS has taken the lead in public reporting by providing easy to understand, clinical data on heart surgery outcomes to the public. The Society’s ongoing collaboration with Consumer Reports seeks to better inform and educate consumers about their options in cardiac care.

Since its inception in 2010, the STS adult cardiac surgery public reporting initiative continues to grow, both in the number of voluntarily enrolled participants and the composite measures offered. STS now publicly reports outcomes for isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement (AVR), and AVR+CABG surgeries.

Model Design

In this proposed model, the accountable entity will be faced with several management risk corridors (MRCs) that will differ greatly across different patient conditions and present many challenges. Below, we describe a few of these disparate MRCs and the pressures that will place financial pressures on the accountable entity's decision-making. None of these hypotheticals situations are intended to imply that the provider in question would have anything other than the best possible care for the patient in mind. However, in order to ensure that the model is effective, we must understand the external pressures it applies on those providing the care. Just as the sustainable growth rate formula emphasized volume of services, so too will the condition episode approach will affect care delivery.

Different benefits and concerns arise when considering whether the primary care provider or the cardiologist should be the accountable entity under the model. Historically, the role of the PCP in the treatment of CAD has been to refer that patient to a cardiologist without any PCP-ordered diagnostic testing. If the PCP is the accountable entity, (s)he will be responsible for the following MRCs among others. The cardiologist will face the same patient MRCs as the PCP but with a greatly expanded knowledge base. However, incentives and disincentives for invasive revascularization will be more complex. The following demonstrate some examples of pros and cons when primary care providers and cardiologists are asked to be the accountable entity:

- 1) After establishment of a diagnosis but prior to a payment year there will be a strong incentive to proceed with diagnostic testing in an accelerated fashion to use these resources before the patient enters a condition payment year. Most PCPs in their current practices may not be prepared to apply AUCs and may "over test" these patients.
- 2) During the condition payment year the PCP will need to make referral decisions to interventional cardiologists/surgeons /hospitals partly based on the costs of services. PCI will favor CABG financially and inappropriate decisions may be made. Cardiologists may also be influenced by episode costs in debatable clinical situations.
- 3) Both PCPs and cardiologists will become purchasers of services, a non-traditional role, that will require large amounts of cost data not currently available and essentially placing them in uncharted waters.
- 4) During the condition payment year but nearing its end the diagnostic work-up for patients with accelerating angina may be delayed until the next payment year.
- 5) Risk corridors for management and pricing of episodes will need to be developed to better direct patient care.

Based on these observations, we offer the following conclusions:

1. Patients with "active" CAD (unstable angina) in their condition year are best managed by cardiology with strict adherence to using a heart team for management of treatment decisions.
2. Public reporting will help the accountable entity to manage appropriate referral practices.

3. There are many nuanced decisions regarding management that may influence costs, especially in the time period prior to the payment year. Therefore, we would suggest that the panel consider including a 2-3 month window prior to the condition payment year to assess the intensity of noninvasive and invasive testing specific to CAD. Whether these are attributed to the condition payment year is a CMS policy decision.
4. Patients with associated documented clinically significant CHF and need for PCI, CABG or ICD should be excluded from the measurement population. Costs will be difficult to control as patients reach end stage ischemic heart disease
5. Begin with an “un-nested” approach for the procedure episode, establishing pricing and management principles for a condition episode and using the management risk corridors as listed above to develop episode pricing risk corridors for PCI and CABG. There are many reasons to exclude pricing for the bundled procedures from the chronic condition payment:
 - a. Historical data does not exist for a complete bundle construction.
 - b. Un-nesting will eliminate conflicts of interest that will exist for revascularization options.
 - c. It will eliminate the need for PCPs or cardiologists to assume the role of payors/purchasers of health services. This is uncharted territory that may best be handled later.
 - d. It will allow payors and providers to establish management bundles and procedural bundles that they are comfortable with and can eventually be rolled together into a true condition episode payment structure.
 - e. It will allow for the development of the provider infrastructure to manage bundles and the associated 2 sided risk.
6. The payment structure must recognize the need for a heart team and assign a distinct payment for this activity which is human resource intensive but has proven overwhelming value (the heart team is used in TAVR, transplantation and currently being used in European centers for CAD).
7. The HCP-LAN should establish a provider advisory council made up of PCPs, cardiologists and cardiac surgeons to assist in establishing these concepts.
8. Use the STSD and ACC databases blended with financial data as in Virginia to develop clinically relevant procedural pricing risk corridors. Reliance on claims data divided into DRGs with and without MCC is not granular enough to describe true risk. Use of these databases will allow better identification of costs associated with complex patients having multiple co-morbidities.

June 20, 2016
Lew Sandy, MD
Page 10

Thank you for the opportunity to submit these comments. If you have any questions, please contact STS Director of Government Relations Courtney Yohe at cyohe@sts.org or 202.787.1222.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph E. Bavaria". The signature is fluid and cursive, with a long horizontal stroke at the end.

Joseph E. Bavaria, MD
President