The Society of Thoracic Surgeons

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Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard Baltimore, Maryland 21244-1850

RE: Cancellation of Advancing Care Coordination through Episode Payment and Cardiac Rehabilitation

On behalf of The Society of Thoracic Surgeons (STS) I write to submit comments on the Cancellation of Advancing Care Coordination through Episode Payment and Cardiac Rehabilitation, published in the *Federal Register* on August 15, 2017. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,300 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within 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 that the Centers for Medicare and Medicaid Services (CMS) have proposed to cancel the Coronary Artery Bypass Graft (CABG) Episode Payment Model (EPM). As STS has previously articulated, we had a number of concerns with the design of the model. However, we do not want to give the impression that our lack of support for the CABG EPM is somehow indicative of a lack of support for value-based payment. In truth, STS has been at the cutting edge of improving quality of care for cardiothoracic surgery patients. Some of our concerns with the proposed CABG EPM signified that the medical specialty society representing the surgeons who would be directly impacted by the proposed payment model felt we could do a better job of driving Medicare value-based payment.

For example, the CABG EPM included a mandatory all-cause mortality measure as one of only two required quality measurements in the CABG EPM. As we pointed out in our comments on the August 2, 2016 proposed rule, the mortality rate for CABG is already at 2%. We questioned how CMS planned to distinguish among EPM participants if 98% of them were already hitting the prescribed quality benchmark. In response to these comments, CMS added the STS-developed CABG Composite Score as an optional quality measure for the CABG EPM. The STS CABG Composite Score is calculated using a combination of 11 measures of quality divided into four broad categories or domains. Importantly, the 11 individual measures and the overall composite measure methodology are all endorsed by the National

Quality Forum (NQF) and have undergone careful scrutiny by quality measure experts. The four domains are:

- Risk-adjusted mortality.
- Risk-adjusted major morbidity, which represents the percentage of patients who leave the hospital with none of the five most serious complications (often referred to as morbidities) of CABG—reoperation, stroke, kidney failure, infection of the chest wound, or prolonged need to be supported by a breathing machine, or ventilator. Some of these complications, such as stroke or kidney failure, are just as important to many patients as whether they survive the surgery, as these outcomes profoundly impact quality of life. Overall, based on data from the STS National Database, about 85 percent of patients are discharged with no such complications.
- The percentage of CABG procedures that include the use of at least one of the arteries from the underside of the chest wall—the internal mammary (or internal thoracic) artery— for bypass grafting. This artery has been shown to function much longer than vein grafts, which can become blocked over time.
- How often all of the four medications believed to improve a patient's immediate and long-term outcomes were prescribed. These medications include betablocking drugs prescribed pre-operatively, as well as aspirin (or similar drugs to prevent graft clotting), and additional beta-blockers and cholesterol-lowering medicines prescribed at discharge.

Additional concerns with the CABG EPM proposal that STS has previously articulated during the rulemaking process include:

- Model Design – The major costs in the CABG bundle are centered around the index admission and physician costs. The CABG EPM model was set up to attempt to extract most of the EPM savings out of the 20 percent of the cost that is accrued after discharge from the index admission. Although there may be efficiencies and cost savings to be found in reducing hospital readmissions and better coordination of post-acute and other outpatient care, all of those costs, combined, still do not make up the majority of the cost under the CABG bundle.

- Risk Adjustment – Methodology for payment should rely on clinical data and the STS Risk Calculator (already utilized by CMS in other settings) rather than claims-based data. Risk adjustment using clinical data is far more reliable and accurate than claims-based risk adjustment. STS has developed highly credible risk adjustment models for mortality and morbidity as clinical outcomes, but risk adjustment models for resource utilization are much less well-developed.

- Clinical Homogeneity –Limiting inclusion in the CABG and acute myocardial infarction (AMI) models to the most clinically similar subset of patients would allow for meaningful comparisons among patients and ultimately provides CMS the opportunity to clearly evaluate the impact of EPMs on patient care and outcomes.

- Confusion over the application of the qualified participant (QP) benchmarks – STS recommended that CMS assess QP status for an APM Entity collectively between the AMI and CABG models. The denominator in the QP calculation for both the AMI model

and CABG model at a given hospital is likely to include the near same patient set; however, assessed separately, the numerators for the QP calculation will essentially be split between the two models, making it more difficult to reach the QP thresholds. Such an approach is also consistent with the highly-desirable and strongly-encouraged concept of the "heart team."

- Concerns over excluded services –Many of the services included in the CABG EPM did not have any clinical relevance to a CABG. Additionally, the list of MSDRG readmissions that would fall into the "related items and services" category would have resulted in services that were clinically unrelated to a CABG being classified to the CABG model.

Despite our concerns with CABG EPM proposal, STS fully intends to continue its long standing practice of supporting innovative ideas to improve health care quality and reduce overall health care costs. The following comments describe the beginnings of an alternative payment model that will provide an opportunity for both cardiac and general thoracic surgeons to participate in an APM. Importantly, our APM proposal makes a number of critical assumptions which include STS's ability to access all the resources and data sources necessary to implement the payment model as described and optimize the STS National Database (ND) to support the payment model. Resources required for effective implementation include access to uninterrupted linkages between the clinical data in the STS National Database and claims data from Medicare (MedPAR data) and other private payors. STS is currently pursing these arrangements though legislative and regulatory advocacy and networking opportunities. The payment model will also require direct access to death information contained in the Social Security Death Master File (SSDMF) or the National Death Index. To date, we have been unable to access these resources. As a result, we have not been able to propose a fully developed APM proposal to CMS, the Center for Medicare and Medicaid Innovation, or the Physician-focused Payment Model Technical Advisory Committee.

STS Alternative Payment Model

STS began work on the following APM specifically related to cardiothoracic disease (including coronary artery bypass grafting (CABG)[1] and valve repair and replacement procedures) and treatments for lung cancer in 2013.[2] Previous data for CABG support the premise that the use of evidence-based team care can avoid unnecessary testing and inappropriate or futile therapy.[3][4] In

[1] The CPT codes most commonly used by STS members in the treatment of CABG-related conditions include the following: 33510-33519, 33521-33523, 33533-33536, 33508, 33530, and 35600.

[2] The CPT codes most commonly used by STS members in the treatment of lung cancer include the following: 32096-32098, 3210, 32440, 32442, 32445, 32480, 32482, 32484, 32486, 32488, 32491, 32501, 32503-32507, 32540, 32663, 32666-32672, 32674, 38746, and 32701.

[3] 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

[4] 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,y, 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

addition, the identification and reduction of high cost postoperative complications can substantially improve quality and reduce spending[5][6][7][8]. These comments provide a high-level summary and frame work for the heart team and lung cancer care team APM.

Heart/Lung Cancer Care Models

STS recommends Medicare adopt a physician-focused APM (PF-APM) that fosters collaboration among a multi-disciplinary team of cardiothoracic care providers. Such a model could use the STS National Database to combine clinical and cost data to develop evidence-based protocols with the goal of improving clinical performance in targeted aspects of care, such as atrial fibrillation prophylaxis, transfusion reduction, early extubation and perioperative glucose management, postoperative wound management among others.[9] The additive cost of complications in cardiac surgery is well described by the Virginia Cardiac Surgery Quality Initiative (VCSQI)[10] and their impact on health care spending is substantial. For example, reductions in postoperative atrial fibrillation (afib) and transfusions through the implementation of statewide protocols have led to substantial savings in the VCSQI program.[11] A combined clinical / financial database tool has been an essential cornerstone of the Virginia project and has been critical to its success[12][13][14][15].

[5] 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.
[6] 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.
[7] LaPar, MD, MS, Damien J., et al. "Postoperative atrial fibrilation significantly increases mortality, hospital readmission, and hospital costs." The Annals of Thoracic Surgery, 2014: 527-533
[8] 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.
[9] Alan M. Speir, MD, Jeffrey B. Rich, MD, Ivan Crosby, MD, and Edwin Fonner, Jr, DrPH,, Regional Collaboration as a Model for Fostering Accountability and Transforming Health Care, Semin Thorac Cardiovasc Surg 21:12-19
[10] VCSQI is a voluntary consortium of 18 hospitals and 14 cardiac surgical practices providing open-heart surgery in the Commonwealth of Virginia. VSCQI's members perform over 99 percent of Virginia's open-heart procedures. The group has convened since 1996, comparing data and exchanging information to improve the quality of surgical care and contain costs. VCSQI helps implement protocols to reduce post-operative complications, was involved in the adoption of quality measures in cardiac surgery for the National Quality Forum, and has formulated policies on pay for performance programs.
[11] Damien J. LaPar, MD, MS, Alan M. Speir, MD, Ivan K. Crosby, MD, Edwin Fonner, Jr, DrPH, Michael Brown, PA-C, Jeffrey B. Rich, MD, Mohammed Quader, MD, John A. Kern, MD, Irving L. Kron, MD, and Gorav Ailawadi, MD,,, Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs, Ann Thorac Surg 2014;98:527–33
[12] 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.
[13] 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.
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[15] 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.

Data: As described above, the STS model aims to blend the STS National Database 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. Although the Virginia model has also had some success accessing cost data from hospitals, a direct linkage to payor data is preferred. Adding unique device identifiers and mortality data form the Social Security Death Master File to this claims information would also yield important information on long-term efficacy of medical devices. 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.

The linked data will also serve as a feedback mechanism for participants. When the STS National Database dashboard feature is fully implemented, STS members will be able to evaluate their respective performances relative to their peers and make adjustments as necessary. The dashboard may also be updated to include important CMS reporting information and other requirements that are embedded in the MACRA legislation so that STS members can not only check on the validity of the data CMS is using to analyze their performance but also react to it in a proactive way. This information could include quality reporting and resource use measures. STS will continue to monitor MACRA implementation and what would be required to incorporate this functionality into the new dashboard feature.

Quality/Cost Metrics: Regardless of the exact payment methodology used (MIPS or APMs), providers are required to report on certain quality measures before they can benefit from any financial incentives established under MACRA. Because STS believes that the best measures of physician performance are generated by physicians using robust clinical information, the Society will continue to develop quality measures for approval by NQF and/or through alternate quality measure development pathways. To date, STS has sponsored more NQF-endorsed quality measures (34) than any other professional organization and include risk-adjusted morbidity and mortality measures that have already driven change and improvements in care for Medicare beneficiaries. Reporting on these measures will be a baseline for quality reporting under the new STS-APM. APM participants would not be able to recoup shared savings or bonus payments under this model unless quality benchmarks using these measures as established by CMS for the Merit-based Incentive Payment System (MIPS) program are met. The STS National Database will maintain its status as a qualified clinical data registry and could report to CMS on quality and resource use measures on behalf of all participants regardless of whether those STS members are participating in the MIPS or the STS APM should they elect to have STS report on their behalf. In addition, future measures should continue to evolve to demonstrate improved patient outcomes and should put a premium on patient reported outcomes, patient experience measures, and patient functional status.

STS APM participants will also be required to comply with established, evidence-based clinical practice guidelines (CPG) and appropriate use criteria (AUC) whenever possible as a baseline for participation in the program. STS follows the Institute of Medicine's standards for developing

CPGs to help ensure that recommendations are evidenced based. The use of CPGs and AUC will be an important tool for the success of the STS APM.

Public Reporting: Participants in the APM could be required to sign up for STS Public Reporting.

Payment Methodology: The framework for payments to providers would be based the current payment structure for the time being. Tracking of spending, outcomes and savings would occur through the database by calculating the ratio of observed to expected costs attributed to a patient's care. Risk adjustment, an essential component of the model, will be accomplished using the STS National Database and the STS Risk Calculator. Cost benchmarks (or the "expected" cost) would be established for "typical" global surgical periods by using historical data.

Once the infrastructure is in place, STS would appoint a panel to annually identify a menu of quality improvement initiatives (QII) for possible implementation by APM participants. Panelists would be expected to review the *Annals of Thoracic Surgery*, the STS flagship journal, and other scholarly articles from peer reviewed journals that utilize the STS National Database. The panelists will select activities that, based on the evidence, have been demonstrated to improve patient outcomes and/or patient experience and are associated with significant cost savings. The panel would identify the cost of implementation of QIIs (downside financial risk). The panel would be required to nominate a certain number of QIIs that include downside financial risk.

The QII panel will include:

- Surgeons
- Patient Representatives
- Payor Representatives
- Hospital Representatives

Participants would be required to select a sub-set of QIIs and implement them over the course of the year. Financial risk in this phase can be measured by implementation cost if there is a cost to implement the QII itself. It can also be observed as a function of the QII. For example, if the QII limits procedures (either deemed to be unnecessary by emerging literature or as a result of improved patient outcomes or decreased complications) which would have resulted in an additional payment under FFS, then that forgone payment counts towards downside risk.

Shared Savings: The main goal of this APM is to drive quality improvement and reduce costs through the creation of standardized treatment protocols and new care delivery models. If the care transformations generate savings relative to agreed-upon benchmarks, then physicians would be allowed to share in those savings. Initially, this would be an upside risk model, where the providers could share in any savings but are not penalized for costs above the benchmark. This model could evolve to a two-sided risk model, where providers would be financially at risk for spending above the benchmark.

Third Party Administrator: Under the Medicare Access and CHIP Reauthorization Act (MACRA) statute, Medicare payments will be made to the APM entity. Additional information

from the regulations implementing MACRA is required to determine how payments will be distributed.

Waivers: Current Medicare rules and regulations may prove a hindrance to these types of provider arrangements (waivers already exist for the ACE demonstration). However, in similar circumstances (e.g., the Medicare Shared Savings Program), Congress has provided a pathway for entities to seek a waiver from certain rules and regulations (e.g., gain-sharing regulations). Members of the heart or lung cancer team, as needed, could seek a waiver to allow them to alter beneficiary cost-sharing in order to provide a financial incentive to encourage beneficiary behavior so that patients accept referral to the heart and lung cancer team and treatment from those team members.

Episodes of Care Development

At the core of any advanced APM is the aggregation of services (and the reimbursement for those services) across providers, venues and even across a population of patients, into a well-defined episode of care. There are a number of initiatives currently underway to develop a process for defining episodes of care.

On the federal level, the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 required CMS to provide confidential resource use reports to physicians. Language in the Affordable Care Act (ACA) of 2010 included a requirement for the development of a publicly available episode grouper. In response to these requirements, CMS engaged the services of a consortium[16] led by Brandeis University in 2012 to develop, over 4 years, a prototype episode grouper system to use for Medicare value-based purchasing. Recently, the American College of Surgeons (ACS) joined forces with Brandeis University and the Center for Surgery and Public Health at Brigham and Women's Hospital, in their efforts to develop a software program that will use Medicare administrative claims data to assign services, based on a condition or treatment (including a surgical procedure) and their associated Medicare payments to clinically relevant episodes of care.

In April, 2017, the Physician-focused Payment Model Technical Advisory Committee (PTAC) deliberated and voted to recommend this proposal for limited-scale testing of the ACS-Brandeis Advanced APM. STS endorsed the ACS-Brandeis submission to PTAC and submitted our thoughts about a heart team and lung team APMs as an addendum to that proposal. **It is our fervent hope that CMS will work with us to implement episode-based payment for the heart and lung team**, perhaps in the context of limited testing of the ACS-Brandeis APM model. Eventually, we hope that the model could be expanded to take on population-based payment. In order to effectively implement this model, the STS clinical/financial tool may need to be combined with the robust clinical information found in the American College of Cardiology's National Cardiovascular Data Registry (NCDR®).

Summary

[16] The consortium also included AMA-PCPI, ABMS, and Health Care Incentives Improvement Institute (HCI3). Acumen, LLC provided contractor support.

STS looks forward to taking a lead role in the creation of PF-APMs that reward providers based on the value, rather than the volume of care they provide to beneficiaries. With a focus on high cost, high impact patients and procedures, STS recommends APMs that incentivize and reward coordination and collaboration among providers. With adoption of the PF-APMs described above, the Medicare program would be creating a system through which all the involved providers are collectively responsible for the care provided. By advancing a model that helps ensure that the patient receives the most appropriate care in the right setting, at the right time, from the most appropriate provider, outcomes should be maximized while extraneous costs should be minimized – goals shared by Congress, CMS, STS, and patients alike.

Because of the reasons articulated above, we support the CMS decision to cancel implementation of the CABG EPM. We do so with full knowledge that any delay will deny cardiothoracic surgeons access to the only relevant alternative payment model approved by CMS as an Advanced APM for the 2017 performance period. This means that most cardiothoracic surgeons will not have a viable option if they want to earn the APM bonus payments available to Advanced APM qualified participants under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) until at least the 2020 payment year. We hope to continue to work with CMS through the CMMI and the Physician-focused Payment Model Technical Advisory Committee (PTAC) to affect speedy implementation of a meaningful, value-driven APM that cardiothoracic surgeons can freely adopt of their own volition. We believe this model will prove to be more effective and less administratively burdensome for the physicians and hospitals than what CMS has proposed.

Thank you for considering our comments. Should you have any questions, please contact STS Director of Government Relations Courtney Yohe at 202-787-1222 or cyohe@sts.org.

Sincerely,

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President