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April 18, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
P.O. Box 8013
Baltimore, Maryland 21244-8013

Via Electronic Submission: <http://www.regulations.gov>

Re: Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model; Delay of Effective Date

Dear Administrator Verma,

On behalf of The Society of Thoracic Surgeons (STS) I write to submit comments on the Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model; Delay of Effective Date, published in the Federal Register on February 17, 2017. Founded in 1964, STS is an international not-for-profit organization representing more than 7,300 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.

In our comment letter dated October 3 (included as Appendix A), we highlight a number of concerns with the Coronary Artery Bypass Graft (CABG) Episode Payment Model (EPM) as originally proposed. We also presented our thoughts during a meeting with staff from the Centers for Medicare and Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI) on September 19, 2016. At that time, leaders from the Society presented some of these ideas and articulated ways that STS and CMS could collaborate to the benefit of Medicare beneficiaries.

While a few of those concerns were addressed in the final rule, numerous other implementation issues remain. We appreciate the willingness of the CMS to postpone implementation of the model until these issues can be resolved and we support delay until January, 2018. 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. In fact, for reasons explained below, we have some doubts as to whether cardiothoracic surgeons will be able to access Advanced APM bonus payments under the proposed CABG EPM anyway. 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.

Further, we continue to object to the mandatory nature of the CABG EPM. While we recognize this may present issues for CMMI as they evaluate the model design, we suggest they use other incentives rather than imposing this burden on facilities that are already struggling to implement new payment requirements and may have focused on other laudable priorities, and thus not be prepared for such a drastic change related to CABG payments.

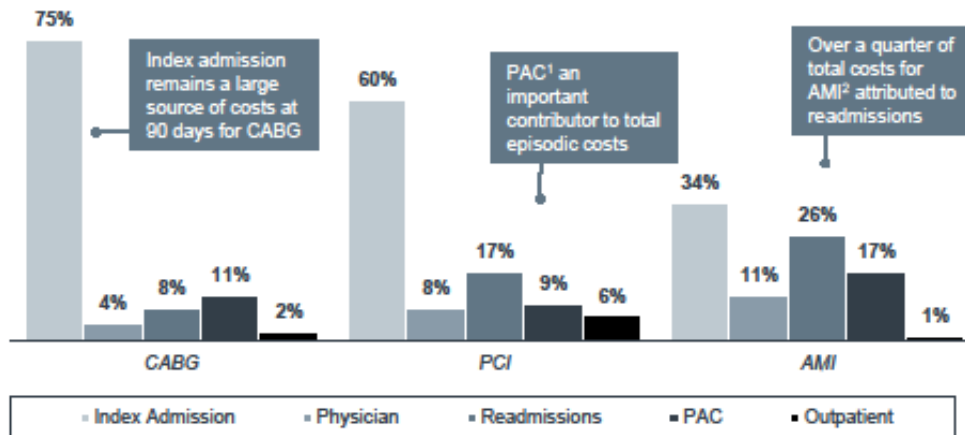
Model Design

Per the chart below, the major costs in the CABG bundle are centered around the index admission and physician costs. The CABG EPM model is 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.

Assessing Costs At 90 Days After Admission

Cardiac and AMI EPMs Would Require Tailored Strategies

Percentage of Total Costs Attributed to Each Setting at 90 Days
Medicare, 2014



1) Post-acute care.

2) Medical treatment of AMI.

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Source: Advisory Board analysis.

STS believes there is a more direct way to influence quality and reduce cost. By combining the clinical information in the STS National Database with claims data we can facilitate quality improvements that will generate savings in ways that the currently proposed models lack. We think APMs should change *how* we pay for care in addition to changing *what* is being paid for. The STS quality-based payment proposal can be implemented either as an intermediate step or, if necessary, in addition to the introduction of a CABG EPM as well as in conjunction with the ACS-Brandeis Advanced APM that the PTAC recently voted to recommend to the Secretary for testing.

Establishing a linkage between Medicare claims and the clinical data in the STS National Database would allow CMS to target the major cost center in the CABG bundle. We firmly believe that if we are able to create a clinical/financial tool by combining the STS National Database with claims data, we can help hospitals and surgeons to improve quality and generate savings in the hospital setting. Further, providing that level of support will also assist the system in reducing post-acute care costs by ensuring that providers have the ability to identify best practices that can help keep patients from requiring care at a Skilled Nursing Facility or Inpatient Rehabilitation Facility to begin with.

More information on the STS National Database is available in our initial comments. We would like to thank CMS and CMMI staff for continuing to work with us on implementation of Section 105(b) of MACRA (Pub. L. 114-10) which **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. We hope implementation issues related to this statutory requirement can be resolved quickly and we look forward to helping in any way we can.

Absent any way to directly influence and control costs under this bundle, surgeons will face pressures to avoid high risk cases that are likely to develop complications. Robust risk adjustment using clinical data will be essential to this program to ensure that participating hospitals that need to transfer admitted patients to another, better equipped participating facility for a CABG are not given a disincentive or even prohibited from ensuring that patients get the best care possible. **Risk 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. 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 have been demonstrated to have major flaws¹², 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 tool available – The STS National Database – rather than insisting on using inferior processes. Use of the STS National Database as a tool to define clinical risk corridors that define financial risk would be the most appropriate tool for patient safety. Without this tool high risk Medicare beneficiaries will certainly be disenfranchised from the medical care that they so desperately need.

EPM-Episode Benchmark and Quality-Adjusted Target Price Features

We remain concerned that CMS has proposed two different but overlapping EPMs in this notice of proposed rulemaking. The acute myocardial infarction (AMI) EPM is a condition-specific bundle while the CABG EPM applies to a specific procedure that is sometimes used to treat patients with AMI. Although CMS has carefully laid out a methodology for scenarios in which patient may transition from one bundle to another, the results of this EPM “experiment,” as it is referred to in the proposed rule, will be skewed because there are effectively two uncontrolled variables being evaluated at the same time.

As such, we join the American College of Cardiology in urging CMS to work with the clinician community to establish clinical homogeneity within the models, limiting ambiguity

¹ Shahian DM, Silverstein T, Lovett AF, et al. Comparison of clinical and administrative data sources for hospital coronary artery bypass graft surgery report cards. *Circulation*. 2007;115:1518-27.

² Mack MJ, Herbert M, Prince S, et al. Does reporting of coronary artery bypass grafting from administrative databases accurately reflect actual clinical outcomes? *J Thorac Cardiovasc Surg*. 2005;129:1309-17.

as much as possible. Limiting inclusion to the most clinically similar subset of patients allows for meaningful comparisons among patients and ultimately provides CMS the opportunity to clearly evaluate the impact of EPMS on patient care and outcomes. CMS must proceed with caution to avoid unintended consequences of the proposed AMI and CABG models and to work with clinicians including cardiothoracic surgeons, cardiologists, and the entire cardiovascular care team to continue to develop and refine the model.

CMS proposes an effective discount factor “to serve as Medicare’s portion of reduced expenditures from an EPM episode with any EPM-episode expenditures below the quality adjusted target price potentially available as reconciliation payments to the EPM participant where the anchor hospitalization occurred.” CMS adjusts these according to four quality performance categories: Excellent, Good, Acceptable, and Below Acceptable.

STS believes that the currently proposed effective discount factors fail to take into consideration the tremendous investments that will be made by the APM Entities that achieve performance scores in the Excellent and Good categories. We urge CMS to reduce its proposed discount by a percentage point to account for these necessary administrative resources.

Advanced Alternative Payment Model (Advanced APM) Considerations

STS appreciates the CMS effort to expand the Advanced APM participation options available to physicians which could increase the likelihood that model participants are eligible for the APM Incentive Payment created under MACRA. As CMS is aware, the APM Incentive Payment is time-limited and there are few current models that offer participation opportunities for surgeons. STS is supportive of CMS thoughtfully but swiftly making models available for participation under this category of APMs.

However, the availability of Advanced APMs does not guarantee access to the incentive payments given the MACRA provisions and CMS proposals related to reaching thresholds based on percentages of revenues or patients associated with care delivered in the context of the Advanced APM in order to become a “Qualifying Participant” or QP. While we are aware that CMS is implementing the MACRA provisions, we believe that in creating siloed EPMS and assessing them as separate Advanced APMs, CMS could be undermining the investments and efforts of Advanced APM participants by making it more difficult to achieve QP status. Therefore, in order to allow CMS to achieve its goals related to implementation of the QP requirements while supporting physician participation and investment in these models, STS recommends 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. Because CMS is forcing hospitals to participate in these models and since every AMI model hospital will also be a CABG model hospital, STS recommends that CMS assess the QP thresholds across both models collectively as an opportunity for participants to achieve the Advanced APM Incentive Payment. Such an

approach is also consistent with the highly-desirable and strongly-encouraged concept of the “heart team.”

EPM-Episode Price Setting Methodologies

CMS intends to set prices by MS-DRG as well as to distinguish between anchor hospitalization costs and post-anchor hospitalization costs. CMS has proposed to identify excluded (unrelated) services rather than included (related) services based on clinical review. CMS is also proposing to follow the same general principles in determining other proposed excluded Part A and Part B services from the EPM episodes that are used in the CJR model. This means excluding unrelated inpatient hospital admissions during the EPM episode by identifying MS-DRGs for exclusion on an EPM-specific basis. Additionally CMS proposes to further exclude unrelated Part B services during the EPM episode based on the diagnosis code on the claim by identifying categories of ICD-CM codes for exclusion (identified by code ranges) on an EPM-specific basis. ICD-9-CM diagnosis code exclusions would apply to historical episodes used to construct EPM-episode benchmark prices, while ICD-10-CM diagnosis code exclusions would apply to EPM episodes during the EPMs’ performance years.

STS reviewed the exclusions file titled “epm-cabgparameters.xlsx” which identifies the following:

- The MS-DRGs that will be used to initiate CABG episodes;
- The ICD-9 and ICD-10 diagnoses codes that will be used to identify CABG performed in the setting of AMI when listed in the principal or secondary position on a claim with a CABG MS-DRG; the primary ICD-9 code ranges for excluded Part B services in the CABG model;
- The primary ICD-10 code ranges for excluded Part B services in the CABG model; the MS-DRGs that are excluded readmissions in the CABG model; PBPM payments that are excluded from CABG model episode calculations; and
- A list of other exclusions.

STS is concerned with the approach used to identify excluded services – identifying only the primary MS-DRG, ICD-9 and ICD-10 code ranges. This process results in over 22,000 ICD-10 diagnoses codes that would be classified as “included” in the CABG model resulting in those services considered as “related items and services” under the CMS proposed methodology. Many of these services do not have any clinical relevance to a CABG. Additionally, the list of MS-DRG readmissions that would fall into the “related items and services” category would also result in services that are clinically unrelated to a CABG being classified to the CABG model since they are not included on the exclusions list.

In order to ensure appropriate costs and resources related to CABG, the exclusions list should be specific (to the code level) to ensure that only services and readmissions that are clinically related to a CABG are included in the episode. STS reviewed the exclusions lists in detail by expanding the proposed ICD-9, ICD-10 and MS-DRG exclusions list and identifying those codes that are not on the exclusions list. In the included attachment(s), STS has identified specific

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codes for each category of codes that should be added to the exclusions list to ensure that only services that are clinically related to a CABG are included in the model.

EPM Quality Measures, public display, and use of quality measures in EPM payment methodology

The CABG EPM proposal includes two quality measures: all-cause mortality and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. **We appreciate that the final rule included revisions to allow EPM participants to opt to use STS CABG Composite Score rather than all-cause mortality.** We hope that any potential efforts to make further changes to the EPM rule would maintain this revision.

Conclusion

The Society has been at the forefront of quality improvement initiatives for many years. As such, we are eager to work with CMS to implement truly impactful alternative payment models that will ensure Medicare beneficiaries have access to the best possible care. 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,



Richard L. Prager, MD
President



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October 3, 2016

Appendix A

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
P.O. Box 8013
Baltimore, Maryland 21244-8013

Via Electronic Submission: <http://www.regulations.gov>

Re: Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Joint Replacement Model (CJR)

Dear Acting Administrator Slavitt:

On behalf of The Society of Thoracic Surgeons (STS) I write to submit comments on the Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) Proposed Rule published in the *Federal Register* on August 2, 2016. Founded in 1964, STS is an international not-for-profit organization representing more than 7,300 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 were concerned that the Centers for Medicare and Medicaid Services (CMS) proposed this mandatory payment model without soliciting STS feedback in advance, given the obvious expertise STS members have in at least two of the proposed models. We have led the way for medicine in documenting and improving care quality, and we have been formally working on a quality-based payment proposal since 2013. Further, we have recently been collaborating with the American College of Surgeons to overlay our quality-based payment principles over their bundled payment design. While the coronary artery bypass graft (CABG) EPM shares some similar characteristics to that joint effort, we feel that the model we hope to propose in the coming months will prove to be more effective and less administratively burdensome for the physicians and hospitals than what CMS has proposed.

At a meeting with staff from the CMS and the Center for Medicare and Medicaid Innovation (CMMI) on September 19, 2016, leaders from the

Society presented some of these ideas and articulated ways that STS and CMS could collaborate to the benefit of Medicare beneficiaries. Those ideas are also shared below.

Advanced Alternative Payment Model (Advanced APM) Considerations

STS appreciates the CMS effort in this proposed rule to expand the Advanced APM participation options available to physicians which could increase the likelihood that model participants are eligible for the APM Incentive Payment created under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). As CMS is aware, the APM Incentive Payment is time-limited and there are few current models that offer participation opportunities for surgeons. STS is supportive of CMS thoughtfully but swiftly making models available for participation under this category of APMs.

However, the availability of Advanced APMs does not guarantee access to the incentive payments given the MACRA provisions and CMS proposals related to reaching thresholds based on percentages of revenues or patients associated with care delivered in the context of the Advanced APM in order to become a “Qualifying Participant” or QP. While we are aware that CMS is implementing the MACRA provisions, we believe that in creating siloed EPMs and assessing them as separate Advanced APMs, CMS could be undermining the investments and efforts of Advanced APM participants by making it more difficult to achieve QP status. Therefore, in order to allow CMS to achieve its goals related to implementation of the QP requirements while supporting physician participation and investment in these models, STS recommends 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. Because CMS is forcing hospitals to participate in these models and since every AMI model hospital will also be a CABG model hospital, STS recommends that CMS assess the QP thresholds across both models collectively as an opportunity for participants to achieve the Advanced APM Incentive Payment. Such an approach is also consistent with the highly-desirable and strongly-encouraged concept of the “heart team.”

Future Directions for Episode Payments

As part of the proposed rule, CMS states that it plans to create a Bundled Payment for Care Initiative (BPCI)-like model reconfigured as an Advanced APM and, seeks input on future designs directed at condition-specific episode payment models that could focus on an acute event, procedure, or longer-term care management, including other models for beneficiaries with coronary artery disease (CAD). CMS also requests feedback on potential models focused on procedures that could be inpatient or outpatient and for episode payment models for hospitalizations for acute medical conditions which could overlap (e.g. sepsis related to pneumonia or acute kidney injury related to congestive heart failure exacerbation).

STS is supportive of these efforts to collect more feedback. In addition to recommending that CMS reconsider the mandatory nature of the current programs, we offer the following input designed to help guide current and future APM development work that would not only lead to better structured programs but also provide organizations such as STS with the tools necessary to help create the types of models CMS says it seeks.

Providing Clinical Databases Access to Claims Data

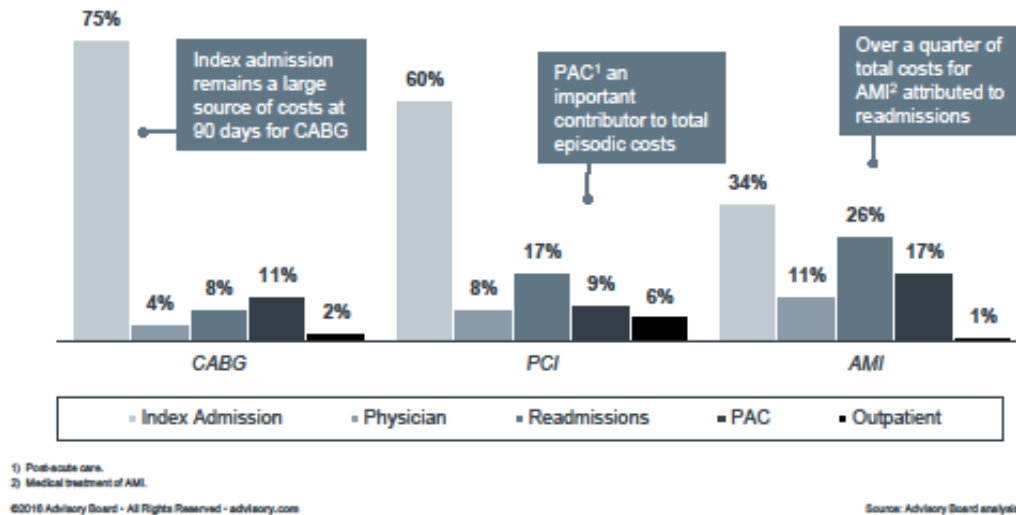
We do not object to bundled-payment, per se, but bundled payment policy is predicated on the notion that bundles will facilitate care coordination and better coordinated care will improve quality and reduce cost. **STS believes there is a more direct way to influence quality and reduce cost. By combining the clinical information in the STS National Database with claims data we can facilitate quality improvements that will generate savings in ways that the currently proposed models lack.** We think alternative payment models should change *how* we pay for care in addition to changing *what* is being paid for. The STS quality-based payment proposal can be implemented either as an intermediate step or, if necessary, in addition to the introduction of a CABG EPM.

Establishing a linkage between Medicare claims and the clinical data in the STS National Database would allow CMS to target the major cost center in the CABG bundle: the index admission and physician costs (see chart below) rather than hoping to extract most of the EPM savings out of the 20 percent of the cost that is accrued after discharge. 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.

Assessing Costs At 90 Days After Admission

Cardiac and AMI EPMs Would Require Tailored Strategies

Percentage of Total Costs Attributed to Each Setting at 90 Days Medicare, 2014



We firmly believe that if we are able to create a clinical/financial tool by combining the STS National Database with claims data, we can help hospitals and surgeons to improve quality and generate savings in the hospital setting. Further, providing that level of support will also assist the system in reducing post-acute care costs by ensuring that providers have the ability to identify best practices that can help keep patients from requiring care at a Skilled Nursing Facility or Inpatient Rehabilitation Facility to begin with.

The STS National Database 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. *The Adult Cardiac Database, the portion of the registry that could be used in support of the proposed CABG APM, has 90 to 95 percent penetration across all the cardiothoracic surgery practices in the country.* This assures a representative benchmark population. In addition to potential utilization of this database in future APMs including a physician-focused payment model (PFPM) that will be proposed by STS in the near future, **we also strongly believe CMS could utilize the STS National Database in the context of the EPM CABG Model and be able to incorporate its**

use without fear of push back from the facilities given the current near-universal use of the database.

Unlike many registries that function solely as data collection and analysis tools, the STS National Database integrates all the functionalities that are dependent upon high-quality data. Using a Task Force structure, the Database incorporates not just quality measurement but also performance improvement, public reporting, appropriateness, resource use, and informatics. This seamless integration maximizes the ability to use STS clinical data for all these related functionalities.

The Duke Clinical Research Institute (DCRI), the world's largest academic research organization, serves as the STS data warehouse and analytical center. STS surgeon members and DCRI statisticians collaborate within the STS Quality Measurement Task Force to develop performance measures. These measures are all published in the peer-reviewed literature and endorsed by National Quality Forum (NQF). However, once the development and endorsement phases have been completed, implementation of these measures to calculate and provide scores for individual programs is done exclusively by DCRI. Even senior STS leaders have no involvement in generating these performance reports, and there is consequently no possibility for any STS member or leader to influence the results.

Clinical registry data, such as those contained in the STS National Database, are unique in several respects. In contrast to EHR data, clinical registry data are highly structured, have standardized and clinically granular definitions, and are entered by highly trained data managers. Each year, more than 500 STS data managers from across the country gather for our annual 3-day Advances in Quality and Outcomes, during which new advances and problematic areas are discussed. Data managers also have continuous access to DCRI and STS staff and surgeons for coding questions. In contrast to claims data, which are primarily designed for billing purposes, STS registry data specifications have been developed by surgeons, who focus on clinical content. Each year, STS contracts with Telligen, a Quality Innovation Network-Quality Improvement Organization (QIN-QIO), to audit 10% of STS Database participant sites. In aggregate, more than 100,000 individual data entries are audited each year with an overall agreement rate of 96-97%, indicating high accuracy.

Harnessing a Combined Clinical/Claims Database to Facilitate Improved Care

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 more efficient and effective ways to treat patients. Clinical data from the STS National Database have 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 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 can generate risk models for cost, develop clinically associated risk cost corridors, and help CMS to structure payment around the provision of high quality care. This would allow us to continuously monitor quality as resource utilization is thoughtfully reduced, thereby identifying a cost/quality inflection point.

For these reasons, we were very concerned with CMS’s interpretation of Section 105(b) of 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. Additional information on this policy is included in Appendices A and B.

We have also encouraged CMS to indicate “fact of death” by matching Medicare claims data with Social Security Death Masterfile (SSDMF) death data (or another source of vital statistics) before providing it to QCDRs. 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.

As mentioned above, VCSQI is an example of how 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 his/her financial cost record for over 98 percent 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.

Similarly, in a forthcoming PFPM proposal, STS 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 reducing excess resource utilization while maintaining quality. Future iterations of this tool could also be linked with other sources of clinical data like the American College of Cardiology’s National Cardiovascular Data Registry

(NCDR®) to facilitate a longitudinal, population management payment model. 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. This payment model could be used in the current fee-for-service payment paradigm and can eventually be used in combination with bundled payments or episode-based payments.

Data-Sharing with Hospitals

The proposed rule includes significant details on how CMS will provide hospitals with claims information and performance data to facilitate successful implementation of the EPMs. It is not clear to us that hospitals have the resources or expertise to analyze these data to more effectively implement an EPM. More importantly, hospitals already allocate considerable resources to supporting data managers to facilitate clinical data reporting to the STS National Database. Because the hospitals have already invested these resources in a superior data tool to evaluate their own quality and performance, the hospitals themselves may prefer to have the claims data processed elsewhere. Further, as explained above, the utility of the claims data is amplified exponentially by combining clinical and claims data sources.

As previously noted, early results from similar BPCI policies have been reported, and we hope that CMS will learn from the experiences of the hospitals that have already engaged in similar data-sharing programs. The BPCI initiative actually recognized the need for a facilitator convener – an entity that serves an administrative and technical assistance function for one or more designated awardees/awardee conveners, and who would not have an agreement with CMS, bear financial risk, or receive any payment from CMS. In the recently-released BPCI report, one interviewee stated,

I would say that probably one of the smartest things that CMS did was permit the facilitators to be part of this program because, at least my observation, it is just too heavy of a lift for individual hospitals to both undertake the care redesign that's necessary over the long run, as well as understand and interpret all of the data and the policies of the program¹.

As CMS has already acknowledged the utility of data analysis, we hope future versions of this proposal will allow participants to benefit from the best information (and resources) available to them.

Proposed Definition of the Episode Initiator and Selected Geographic Areas

When selecting hospitals for the mandatory CABG EPM, STS recommends that CMS apply a low volume exclusionary threshold for both CABG and AMI episodes. We understand that CMS is trying to test EPMs at hospitals with different CABG volumes and to test the cardiac EPMs together. However, as highlighted in a recent piece from Singletrack Analytics, episode volume

¹ Group, Lewin. "CMS Bundled Payments for Care Improvements Initiative Models 2-4: Year 2 Evaluation and Monitoring Annual Report." August 2016: 89.

is an important factor in “financial stability and creating critical mass for program success.”² For example, in explaining how high volume creates financial stability, the article states that “hospitals having fewer than 20 episodes per quarter will have their quarterly average episode costs vary by more than +/-10% due to random variation in episode costs, which hospitals having more than 100 episodes in a quarter will have less than half of that amount of random variation.” Additionally, the article emphasizes that developing effective care management programs for an episode is a costly undertaking. With low episode volume, the resulting savings may be insufficient to recoup the costs of these programs. For these reasons, we ask that CMS exclude MSAs with less than 20 CABG episodes per quarter rather than basing the exclusionary criteria only on AMI volume.

Special Policies for Hospital Transfers of Beneficiaries with AMI

Hospital-to-hospital transfers are common for beneficiaries being treated for cardiac conditions. As such, CMS proposes an overarching policy in which episodes involving a “chained anchor stay” would be attributed to the first participant hospital to which the beneficiary is admitted. However, if the patient’s discharge MS-DRG from the receiving hospital is not one of the eligible cardiac model MS-DRGs, the episode would be cancelled. **STS supports this proposal to cancel episodes that include a chained anchor stay but have a final discharge MS-DRG that is ineligible for the cardiac model.**

Patients who have to be transferred from one institution to another very often are a select group of sicker and more complicated patients who are transferred for very specialized care that is not generally available in many hospitals. As a consequence, these patients represent an 'adversely selected' group of patients for whom it would be inappropriate to include in the general categories of AMI or CABG. The American Hospital Association (AHA) found that hospitals that transfer frequently are more likely to be smaller community hospitals. These hospitals have a much higher episode spending relative to their target price than other hospitals, which demonstrates a clear disadvantage for hospital that transfer frequently under CMS’s proposed transfer policy. The same trend was found for CABG episodes. These small community hospitals often have no choice but to transfer their most complicated patients to larger, tertiary or quaternary hospitals so that they can receive the most appropriate cardiac care – they should not be penalized for doing so.

AHA found that AMI model spending for episodes without a CABG readmission, but with a chained anchor stay, averaged almost \$6,000 more than episodes of the same type without chained stays. They also found that this payment differential largely reflected the amount paid for the initial hospital stay. These trends also occurred with CABG episodes. Therefore, in order to avoid inappropriately penalizing hospitals for transferring patients, we recommend that CMS exclude the amount paid to the initially admitting hospital when calculating target prices and actual episode spending. We believe that doing so would help put all hospitals on a more level playing field and encourage the best provision of care.

² Pearce, Jonathan, CFA, FHFMA. "Singletrack Analytics." Risks and Opportunities in Medicare’s Cardiac Bundled Payment Program. 8 10, 2016. <http://www.singletrackanalytics.com/blog/16-08-10/risks-and-opportunities-medicare%E2%80%99s-cardiac-bundled-payment-program> (accessed 9 26, 2016).

As mentioned above, bundled payment, alone, is not likely to be able to help hospitals control costs, particularly in the CABG bundle. Absent any way to help control costs under this bundle, surgeons will face pressures to avoid high risk cases that are likely to develop complications. Robust risk adjustment using clinical data will be essential to this program to ensure that participating hospitals that need to transfer admitted patients to another, better equipped participating facility for a CABG are not given a disincentive or even prohibited from ensuring that patients get the best care possible. It will also help to make sure that the “anchor hospital,” in this case, does not have a disincentive to admit and stabilize a complex patient before transferring him to another facility.

Risk methodology for payment should rely on clinical data and the STS Risk Calculator (already utilized by CMS in other settings) rather than claims. Risk adjustment using clinical data is far more reliable and accurate than claims-based risk adjustment. 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. 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 have been demonstrated to have major flaws³⁴, 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 tool available – The STS National Database – rather than insisting on using inferior processes. 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. Without this tool high risk Medicare beneficiaries will certainly be disenfranchised from the medical care that they so desperately need.

EPM-Episode Price Setting Methodologies

CMS intends to set prices by MS-DRG as well as to distinguish between anchor hospitalization costs and post-anchor hospitalization costs. CMS has proposed to identify excluded (unrelated) services rather than included (related) services based on clinical review. CMS is also proposing to follow the same general principles in determining other proposed excluded Part A and Part B services from the EPM episodes that are used in the CJR model. This means excluding unrelated inpatient hospital admissions during the EPM episode by identifying MS-DRGs for exclusion on an EPM-specific basis. Additionally CMS proposes to further exclude unrelated Part B services during the EPM episode based on the diagnosis code on the claim by identifying categories of ICD-CM codes for exclusion (identified by code ranges) on an EPM-specific basis. ICD-9-CM diagnosis code exclusions would apply to historical episodes used to construct EPM-episode benchmark prices, while ICD-10-CM diagnosis code exclusions would apply to EPM episodes during the EPMs’ performance years.

³ Shahian DM, Silverstein T, Lovett AF, et al. Comparison of clinical and administrative data sources for hospital coronary artery bypass graft surgery report cards. *Circulation*. 2007;115:1518-27.

⁴ Mack MJ, Herbert M, Prince S, et al. Does reporting of coronary artery bypass grafting from administrative databases accurately reflect actual clinical outcomes? *J Thorac Cardiovasc Surg*. 2005;129:1309-17.

STS reviewed the exclusions file titled “epm-cabgparameters.xlsx” which identifies the following:

- The MS-DRGs that will be used to initiate CABG episodes;
- The ICD-9 and ICD-10 diagnoses codes that will be used to identify CABG performed in the setting of AMI when listed in the principal or secondary position on a claim with a CABG MS-DRG; the primary ICD-9 code ranges for excluded Part B services in the CABG model;
- The primary ICD-10 code ranges for excluded Part B services in the CABG model; the MS-DRGs that are excluded readmissions in the CABG model; PBPM payments that are excluded from CABG model episode calculations; and
- A list of other exclusions.

STS is concerned with the approach used to identify excluded services – identifying only the primary MS-DRG, ICD-9 and ICD-10 code ranges. This process results in over 22,000 ICD-10 diagnoses codes that would be classified as “included” in the CABG model resulting in those services considered as “related items and services” under the CMS proposed methodology. Many of these services do not have any clinical relevance to a CABG. Additionally, the list of MS-DRG readmissions that would fall into the “related items and services” category would also result in services that are clinically unrelated to a CABG being classified to the CABG model since they are not included on the exclusions list.

In order to ensure appropriate costs and resources related to CABG, the exclusions list should be specific (to the code level) to ensure that only services and readmissions that are clinically related to a CABG are included in the episode. STS reviewed the exclusions lists in detail by expanding the proposed ICD-9, ICD-10 and MS-DRG exclusions list and identifying those codes that are not on the exclusions list. In the included attachment(s), STS has identified specific codes for each category of codes that should be added to the exclusions list to ensure that only services that are clinically related to a CABG are included in the model.

EPM-Episode Benchmark and Quality-Adjusted Target Price Features

In addition to our own APM development work, we have been closely monitoring the implementation of various BPCI payment models. According to a recent report⁵, it is difficult to draw definitive conclusions about the individual models, particularly in the cardiovascular bundles, without rolling them all together. This could result in overgeneralization of results in an area of medicine that has a very broad spectrum of care options. We are similarly concerned that CMS has proposed two different but overlapping EPMs in this notice of proposed rulemaking. The acute myocardial infarction (AMI) EPM is a condition-specific bundle while the CABG EPM applies to a specific procedure that is sometimes used to treat patients with AMI. Although CMS has carefully laid out a care pathway for patients who may transition from one bundle to another, the results of this EPM “experiment,” as it is referred to in the proposed rule, will be

⁵ Group, Lewin. "CMS Bundled Payments for Care Improvements Initiative Models 2-4: Year 2 Evaluation and Monitoring Annual Report." August 2016: 89.

skewed because there are effectively two uncontrolled variables being evaluated at the same time.

As such, we join the American College of Cardiology in urging CMS to work with the clinician community to establish clinical homogeneity within the models, limiting ambiguity as much as possible. Limiting inclusion to the most clinically similar subset of patients allows for meaningful comparisons among patients and ultimately provides CMS the opportunity to clearly evaluate the impact of EPMS on patient care and outcomes. CMS must proceed with caution to avoid unintended consequences of the proposed AMI and CABG models and to work with clinicians including cardiothoracic surgeons, cardiologists and the entire cardiovascular care team to continue to develop and refine the model. Specific recommendations regarding the proposed CABG EPM DRGs are listed below.

CMS proposes an effective discount factor “to serve as Medicare’s portion of reduced expenditures from an EPM episode with any EPM-episode expenditures below the quality adjusted target price potentially available as reconciliation payments to the EPM participant where the anchor hospitalization occurred.” CMS adjusts these according to four quality performance categories: Excellent, Good, Acceptable, and Below Acceptable.

STS believes that the currently proposed effective discount factors fail to take into consideration the tremendous investments that will be made by the APM Entities that achieve performance scores in the Excellent and Good categories. We urge CMS to reduce its proposed discount by a percentage point. As noted above, about three-quarters of CABG episode spending is attributable to the initial hospitalization. This is problematic because there is virtually no opportunity to achieve efficiencies with this inpatient hospital payment amount – it is a predetermined per-discharge payment based primarily on the patient's condition, not on services provided. And, there is obviously no opportunity to achieve efficiencies by eliminating it because then no episode would be initiated.

In addition, for CABGs, of the 25 percent of episode spending that occurs outside the initial hospitalization, about 5 percentage points is attributable to readmissions. We are similarly concerned that hospitals have a limited ability to achieve efficiencies in this area. Specifically, hospitals have done an enormous amount of work over the past decade to drive down cardiac readmissions. As a result, most that occur today are clinically appropriate and necessary - they are not readmissions that should be eliminated. The work hospitals have done has been spurred by, among other things, their public reporting of cardiac readmissions quality measures since 2009. In addition, AMI and congestive heart failure readmissions measures have been included in the Hospital Readmissions Reduction Program (HRRP) since its inception on Oct. 1, 2012, four years ago.

In fact, largely as a result of the HRRP, CMS itself recently touted the fact that hospitals in 49 states and the District of Columbia have cut hospital readmission rates for Medicare enrollees since 2010, with hospitals in nearly a dozen states cutting avoidable readmission rates by more than 10 percent. Researchers recently published similar findings, determining that readmissions rates for AMI, heart failure, and pneumonia were decreasing before the Affordable Care Act

(ACA) created the HRRP. These rates fell even more rapidly after passage of the ACA and have continued since. Other CMS efforts, such as Hospital Engagement Networks, have also aided hospitals in reducing readmissions. Researchers note that at the passage of the ACA, readmission rates fell for conditions targeted by the law and as well as those not targeted by the law, which implies that changes in care in response to the HRRP may have had an effect beyond the targeted conditions.

As such, we are concerned that it will be difficult to impossible for hospitals to reasonably meet or exceed the proposed discount factors by achieving efficiencies in the very limited 20 and 33 percent of spending that occurs outside the initial hospitalization and readmissions for CABG and AMI episodes, respectively. This is especially true over time, as target prices decline further and further. To avoid turning this cardiac model into a thinly disguised payment cut, CMS must provide hospitals with a fair opportunity to achieve enough savings to garner a reconciliation payment.

EPM Quality Measures, public display, and use of quality measures in EPM payment methodology

The CABG EPM proposal includes two quality measures: all-cause mortality and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. **EPM participants should have the option to use STS CABG Composite Score rather than all-cause mortality.** The STS CABG Composite Score is calculated using a combination of 11 measures of quality divided into four broad categories or domains.

- The first domain is risk-adjusted mortality;
- The second domain is 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 third domain measures 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.
- The final domain measures how often all of the four medications believed to improve a patient’s immediate and long-term outcomes were prescribed. Those drugs include beta-blocking 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.

Importantly, the 11 individual measures and the overall composite measure methodology are all endorsed by the NQF and have undergone careful scrutiny by quality measure experts.

In addition, more than 50 percent of adult cardiothoracic surgery programs voluntarily participate in STS Public Reporting Online, which is also published in Consumer Reports. STS Public Reporting Online lists participants' scores for each of the four domains and the STS CABG overall composite score. Each of these numerical scores can be compared with the average scores for all participants in the Database. Participants also have a star rating. The star rating calculation begins by assuming all providers are average and then determines statistically if there is at least a 99 percent probability that the performance of any specific provider is worse than expected (one star) or better than expected (three star). For the several years that STS has been calculating these scores, about 10-15 percent of all Adult Cardiac Surgery Database participants have been one-star, about 10-15 percent have been three-star, and the remainder have been two-star, or average programs.

The CABG Composite Score is more comprehensive than mortality and is already used by 90 to 95 percent of all cardiothoracic surgery programs (although as mentioned, it still includes mortality), so CMS will not lose access to mortality data if it accepts the use of the CABG Composite as an alternative to the mortality measure). Importantly, it also helps to mitigate sample size concerns, as it effectively provides many more endpoints. CABG mortality is already very low – approximately 1 percent. Attempting to distinguish performance differences using this measure alone would be statistically challenging and would yield few high or low performing outliers.

We also believe the more rigorous quality metric should be given more weight overall. **Therefore, if participants opt to use the CABG Composite Score, we recommend that HCAHPS should only be 15 percent of the overall quality score.**

CMS proposes to use a combination scoring approach that would account for both performance achievement and improvement. **STS supports the proposal to reward for both achievement and improvement in quality performance. However, we would encourage CMS to give more weight to the quality improvement in the overall quality score, particularly if the more robust CABG Composite Score is used.**

CMS also proposes to assign EPM participants to the 50th performance percentile of the measure result if they are a low volume program and are unable to produce a reportable value for the measure; if they are a new hospital; and for EPM participants for which CMS has suppressed the measure value due to error. **We support this proposal and appreciate that CMS is making sure that participants are not disadvantaged based on these factors when, in actuality, that participant may have provided high quality care.**

Monitoring and Beneficiary Protection

We ask that CMS either allow the hospitals and surgeons to have more control over which facilities their patients choose for post-acute care or allow post-acute care costs to be excluded from the bundle if the patient chooses a facility that is not recommended by the hospital or surgeon. While patient choice and comfort should always be protected, the surgeon /

hospital should not be held accountable if the patient chooses a sub-optimal post-discharge facility. We are concerned that CMS makes no provision to account for this in its methodology for comparing actual spending to target spending, and therefore, CMS should provide hospitals and surgeons with tools to encourage the provision of care from providers that have affirmatively chosen to be partners in the program and that have demonstrated high quality, efficient care. Surgeons and hospitals must be allowed to preferentially recommend post-acute care facilities that they have evaluated and work with to provide higher quality, lower cost care.

General Concerns

We also feel it is important to comment on the context in which CMS has proposed to implement these potentially disruptive mandatory models. As CMS is aware, 2017 is a year of drastic change in the reporting and performance requirements to which physicians will be subject due to MACRA. While STS welcomed the elimination of the Medicare Sustainable Growth Rate (SGR) formula, we are also mindful of the education and resources that come with the implementation of an entirely new Medicare physician payment update system. For instance, although a QP in an Advanced APM would not be scored under the Merit-based Incentive Payment System (MIPS), potential QPs must continue to report under MIPS in the event they do not meet the QP thresholds. STS, like individual eligible clinicians, will have no way of knowing how their payments will eventually be updated at the time that reporting requirements are expected to be met. Therefore, we must educate them on all potential scenarios and the complex maze of distinct associated requirements. CMS has simultaneously proposed so many changes in payment policy related to services provided by cardiothoracic surgeons that it is not reasonable to have an expectation of success without advanced education and clinical-financial tools attainable through a blend of the STS database and CMS claims data

As a result, **STS urges CMS to provide relief from the compounding and conflicting administrative requirements of multiple, competing programs.** Without significant changes, our members will be pressured to comply with an enormous amount of burden posed by the following mandates:

- Different bundled payments including the Mandatory CABG EPM, the Health Care Payment Learning and Action Network (HCP-LAN) cardiac care episode payment model proposal (still to be determined if it will be implemented), and other APMs adopted by hospitals (e.g. BPCI and Private payor APMs), in addition to the similarly focused, but distinctly crafted MIPS episode-based resource use measures.
- Global payments data collection: Section 523 of MACRA calls for CMS to gather information needed to value surgical services from a "*representative sample*" of physicians. Beginning in 2019, CMS must use these data to facilitate accurate valuation of surgical services. Despite this Congressional mandate, in the proposed rule for the CY 2017 Medicare PFS, CMS announced its plans to collect data for all 10- and 90-day global surgery services from all physicians who perform these services, rather than from a "representative sample" of physicians, which was required by MACRA.

The scope of the data collection proposed in the Medicare PFS far exceeds the data collection that MACRA authorized CMS to carry out. MACRA directed CMS to collect

data from a “representative sample” of physicians. The proposal would require all surgeons to submit data in 10-minute increments for all 10- and 90-day global surgery code services through the use of eight non-payable G-codes. The proposal will impose an undue administrative burden on physicians, disproportionately directing provider resources toward compliance and away from patient care. At a time when physicians are already overburdened with administrative tasks and facing the challenges of implementing wholesale payment reform under one or more of the programs listed above, this data collection requirement is likely to both push surgeons out of practice and fail to yield useful data. A recent study found that, even under current requirements, for every hour physicians provide direct clinical face time to patients, nearly two additional hours is spent on EHR and desk work within the clinic day. Outside office hours, physicians spend another one to two hours of personal time each night doing additional computer and other clerical work.⁶

The resources required for our Society to help prepare our members for success under all of these disparate programs, with little or no practical guidance from CMS to date, are finite. While STS will continue to make every effort to provide the resources our members need to be well-educated on these programs and initiatives, the scope and number of these CMS mandates have made this a nearly impossible task. Despite the best efforts of STS and other organizations, most practicing cardiothoracic surgeons have no idea what is going to be required of them under the MIPS, not to mention the new data collection requirements for global payments and now the new CABG EPM bundle. They will be overwhelmed with new program requirements. As such, our goal as a professional society supporting cardiothoracic surgeons to help design a payment methodology (or physician-focused payment model) that will allow our members to excel and their patients to receive the best possible care is constantly derailed by CMS’s numerous and overlapping proposals. We must shift efforts to help our members understand the morass of additional documentation required of them, even though it may not result in any clinical efficiencies or improvement. Reducing the administrative burden on surgeons will assist us in helping CMS and our mutual society partners to innovate.

⁶ Sinsky, Christine, MD, et al. "Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties." *Annals of Internal Medicine*, 2016.

October 3, 2016
Acting Administrator Slavitt
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Conclusion

The Society has been at the forefront of quality improvement initiatives for many years. As such, we are eager to work with CMS to implement truly impactful alternative payment models that will ensure Medicare beneficiaries have access to the best possible care. 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,

A handwritten signature in black ink, appearing to read "Joe Bavaria", with a stylized flourish at the end.

Joseph E. Bavaria, MD
President