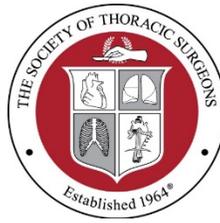


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September 10, 2018

Submitted electronically via www.regulations.gov

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1693-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: [CMS-2018-0076-0621] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma,

On behalf of the members of The Society of Thoracic Surgeons (STS), I am writing to provide comments on the CY2019 Medicare Physician Fee Schedule proposed rule, which was published in the *Federal Register* on July 27, 2018. STS appreciates the opportunity to provide feedback on proposed policies related to the CY 2019 physician fee schedule (PFS), the request for information on price transparency, and the implementation of Year 3 of the Quality Payment Program (QPP).

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,500 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

I. Provisions of the Proposed Rule for PFS

Determination of Practice Expense Relative Value Units (PE RVUs)

STS is concerned with how CMS has allocated time associated with the standard clinical labor tasks. While the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) Practice Expense (PE) Subcommittee has assigned standard times for certain clinical activities, it has always recognized that each service requires different clinical labor resources. The RUC PE Subcommittee recognizes clinical activities may vary depending on the context of the service provided, and in their review of additional work over the standards, they carefully review if different types of clinical work are required. When specialty societies submit recommendations for additional time over the standards, they are required to include supporting rationales. The PE Subcommittee carefully considers these recommendations and evaluates the additional work involved. **STS encourages CMS to focus on the rationale that the specialties and the PE Subcommittee provide in the PE Summary of**

Recommendation and during discussions at the PE Subcommittee meetings when addressing implementation of standard clinical labor tasks.

Determination of Malpractice Relative Value Units (RVUs)

Low Volume Override

STS appreciates that CMS has addressed many, but not all, of the malpractice (MP) Professional Liability Insurance (PLI) RVU issues for the low volume services outlined in our comments in the CY2018 Physician Fee Schedule. These issues included requests to make changes in specialty assignments for identified codes in the low volume service list to reflect the PLI for the specialty that performs the procedure, adding codes with the associated specialty that were missing from the low specialty override list, and correcting the malpractice (PLI) RVU errors for the low volume thoracic surgery and congenital heart surgery codes where the specialty override was not applied even though the services were listed in the low specialty override list. However, there are four codes that are still not included in the proposed CY2019 low volume override list. Therefore, **STS recommends that the following low volume procedures be added to the override list with the indicated and specialty assignment: Cardiac surgery: 35812; Thoracic Surgery: 32654, 33025 and 33251.**

Despite identifying codes in the list of the *CY2019 Anticipated Specialty Assignment for Low Volume Services*, the malpractice RVUs listed in the *Addendum B Relative Value Units and Related Information* indicates that the appropriate low volume overrides were *not applied* to the following congenital/pediatric cardiac surgery codes: 33750 (Blalock Taussig shunt between the subclavian artery and the pulmonary artery, historically the *first surgical procedure for blue babies*) (2018 MP RVU - 5.23; 2019 P MP RVU – 2.42), 33780 (arterial switch operation and closure of a ventricular septal defect repair for transposition of the great arteries with ventricular septal defect, typically carried out in the first month of life) (2018 MP RVU – 10.29; 2019 P MP RVU – 8.42), 33813 (surgical repair of a congenital defect in the wall between the aorta and pulmonary artery) (2018 MP RVU - 5.02; 2019 P MP RVU – 3.46) and 33776 (surgical repair of transposition of the great arteries at the atrial level) (2018 MP RVU – 8.17; 2019 P MP RVU – 6.66). Each of these operations are only performed by congenital heart surgeons who could be classified as either cardiac or thoracic surgeons.

As STS has indicated in previous comments, we support the CMS proposal to use service-level overrides to determine specialty mix for low volume services using the specialty component for both PE and PLI. We appreciate the efforts that CMS has made to ensure that the correct override specialty is assigned to the low volume services as recommended by the specialty societies and the RUC. **We encourage CMS to continue refining their processes to ensure that these overrides are consistently and accurately implemented each year and updated when applicable.**

Premium Data Collection and Determination of PLI RVUs

In the proposed rule, CMS continues to seek input on the next malpractice RVU update due to occur in CY 2020. CMS seeks specific comment on ways to improve how specialties in the state-level raw rate filings data are crosswalked for categorization into CMS specialty codes in order to develop the specialty-level risk factors and the MP RVUs.

Significant comments have been submitted regarding the accuracy of the premium data collection. STS continues to believe that CMS should use updated data for the PLI Premium Update when available, provided that the data and methodology used result in MP RVUs that are as accurate as possible for all specialties. Similar to other specialties, STS has concerns with the data collection process and believes that CMS should be able to obtain premium information for Medicare physician specialties from all fifty

states. STS is aware that even within a given state, malpractice premiums for the same specialties will vary by region. We also have concerns regarding the sources of data utilized for PLI premiums and urge CMS to make a more concerted effort to obtain more broadly based surgical premium data that more accurately reflect the actual malpractice premiums that are being paid. We encourage CMS to review the potential use of other data sources in determining how best to collect PLI premium data in the future:

- Physicians Insurers Association of America (PIAA) - The insurance industry trade association that represents a full range of entities doing business in the medical professional liability arena
- Large national PLI brokers (for example, Gallagher, Marsh) - Large national PLI brokers will have data on premiums for physicians they insure
- Large health care systems (for example, Kaiser) - Large medical groups/systems whose physicians do not pay premiums as individuals, but where the costs of malpractice insurance for different specialties within their group/system are known
- Individual physicians - Data on malpractice premiums can be obtained directly from physicians and other providers by survey or submission of malpractice premium statements.
- Medical Group Management Association (MGMA)
- CMS Survey of specialty societies, physicians, and allied health professionals with analysis of the data on malpractice premiums by geographic region, similar to the methodology to calculate GPCI payment differences.

In addition to the data collection and the data sources outlined above, STS would like to reiterate that the methodology used to determine the MP RVUS is important in determining the correct MP RVUs. Currently there are numerous inconsistencies in the CMS malpractice risk factor table included in the proposed rule. Many of these inconsistencies are counterintuitive. For example:

- diagnostic radiology and interventional radiology have the same non-surgical and surgical risk factors (2.56),
- Neurology and neurosurgery have same surgical risk factor (12.27),
- General surgery has a higher risk factor (7.18) than either cardiac surgery (6.97) or thoracic surgery (7.02)
- Vascular surgery and cardiac surgery have almost the same risk factors (6.97 and 6.84)
- The thoracic surgery risk factor (7.02) is higher than the cardiac surgery risk factor (6.97)

While STS agrees that the cardiology surgical risk factor should be higher than their non-surgical risk factor (1.93) and has recommended that CMS crosswalk for the cardiology surgical risk factor to that of cardiac surgery, in lieu of data that could be used to determine an appropriate risk factor in CY 2018, we expect that the risk factors for cardiac surgery and interventional cardiology will have some differences with a more in-depth analysis of the malpractice premium data.

As CMS evaluates methodologies for use in calculating the MP RVUS, **STS strongly encourages CMS to avoid using population weighting as has been proposed in previous rulemaking.** Population weighting does not reflect the variances in risk-of-service in different areas of the country and will negatively affect clinicians. Geographic premium rate differences are based on risk and paid claims. They are not based on how many people live in a geographic area. In the absence of actual data on geographic

variations in malpractice premiums paid by various specialties, STS believes malpractice RVU's would be better normalized using surgical and non-surgical work RVUs for each geographic area. In this context, STS wishes to remind CMS that risk of a procedure is a component of the work RVU determination. Recognizing risk-of-service provides a more accurate reflection of how services may differ and will better inform professional medical liability policies. Considering time, intensity (including risk), and difficulty of the service is imperative to understanding malpractice risk. Currently, the work RVUs reflect differences in time, intensity (including risk), and difficulty among procedures. **STS believes that these work RVUs currently provide a more accurate substitution for weighting geographic differences to calculate national average premiums. STS strongly encourages CMS to work with The AMA RUC and the national specialty societies to make the MP RVUs as accurate as possible for all specialties.**

Medicare Telehealth Services

STS agrees with the proposal to add codes G0513 (*Prolonged preventive service(s)*) and G0514 (*Prolonged preventive service(s)*) to the telehealth list for CY 2019. Both services are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services and all components of the services can be furnished via interactive telecommunications technology.

STS agrees with CMS that the *Initial Hospital Care Services (99221, 99222 and 99223)* should not be added to the list of telehealth services. STS agrees that it is important to maintain the direct patient interaction for some services. The admitting practitioner, who will have ongoing responsibility for the patient during the hospital stay, should conduct the admission in-person to ensure that the patient's condition upon admission to the hospital is comprehensively assessed.

STS also supports the proposal to maintain the telehealth frequency limitation for *Subsequent Hospital Care Services (99231, 99232 and 99233)* to be billed via telehealth once every 3 days. STS recognizes that it is important for all practitioners (not just the admitting practitioner) involved in the patient's care to make appropriate in-person visits during the patient's hospitalization

Potentially Misvalued Services under the PFS

Update on the Global Surgery Data Collection

As required by the Medicare Access and CHIP Reauthorization Act (MACRA), CMS implemented a process for collecting data on the number and level of post-op visits related to 10- and 90-day global codes. CMS provided several reporting statistics in the proposed rule from states where reporting was required. Of the clinicians who were required to report CPT code 99024 for post-operative visits based on the policy effective July 1, 2017, only 45 percent reported one or more visits during the first six-month period ending December 31, 2017. Among 10-day global procedures performed in that window, only 4 percent had one or more matched visits reported with CPT code 99024. CMS indicated that it is possible that clinicians are not consistently reporting post-operative visits but did not rule out the possibility that post-operative visits are not being provided if not reported, especially in the case of 10-day global procedures.

STS joined the American College of Surgeons (ACS) and a number of other surgical specialty societies to inform our members of the global codes data collection reporting requirements leading up to July 1, 2017 and afterwards. Despite our best efforts, however, it is highly unlikely that all clinicians who are required to report are doing so for every post-operative visit for every procedure. Anything short of perfect reporting will result in inaccurate data that should not be used to revalue global codes. We believe that

CMS has met the MACRA requirements to collect data on the number of post-operative visits. CMS has indicated that it will soon be surveying three additional codes for data related to the level of visits—we believe this will satisfy the data collection portion of the law. MACRA also requires that CMS “improve the accuracy” of global codes based on the data that are collected or other available data.^[1] **STS does not believe that the data that have been collected can be used to improve the accuracy of the existing codes, and we urge CMS not to proceed with revaluing global codes at this time.**

Valuation of Specific Codes

Proposed Valuation of Specific Codes for CY 2019

(12) Aortoventriculoplasty with Pulmonary Autograft (CPT code 335X1)

STS has no objections to the CMS proposal to refine the preservice clinical labor times for the Direct PE inputs for code 335X1 to match the 90-day global procedure standards and adding 15 minutes of clinical labor time to activity code CA008 “Perform regulatory mandated quality assurance activity (pre-service).” STS distributed the additional time in the PE recommendation, per the clinical activities involved, in this complex congenital cardiac procedure. These activities include the clinical labor time associated with additional coordination between multiple specialties prior to patient arrival, securing the correct homograft sizes and specialized equipment used to thaw and wash the homograft, and providing education and obtaining/witnessing consent from the family for this double cardiac valve procedure. The new PE spreadsheets provide additional details, but it is not yet clear how to assign additional clinical staff time within the activity codes. We ask that direction on when changes to the standard times will be recognized. If CMS intends to maintain the 90-day global standards for the clinical labor times, guidance on how additional clinical staff time should be allocated to other activity codes such as CA008 “Perform regulatory mandated quality assurance activity (pre-service)” would be beneficial in ensuring appropriate capture and allocation of clinical labor activities.

(13) Hemi-Aortic Arch Replacement (CPT code 33X01)

CPT code 33X01 *Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion* is an add-on code that was created to account for work that is occasionally performed in conjunction with ascending aortic repairs (current CPT codes 33860, 33863 and 33864). The add-on code represents work in the arch that is similar to, but not as comprehensive as a transverse arch graft (33870). STS surveyed the add-on code 33X01 for the January 2018 RUC meeting independent of the primary procedures because we felt that the “hemiarch” code represented new and different work that is not specifically associated with the work of the ascending aortic procedures. The RUC reviewed the survey with 61 respondents and agreed with the specialty society recommendation of the 25th percentile work RVW, which was 19.74. The RUC recommended an interim work RVW of 19.74 to CMS pending the specialties survey of the hemiarch code in addition to the rest of the ascending and transverse arch grafting services for review at the April 2019 RUC meeting. In reviewing the services, STS determined that, since the codes were to be resurveyed, it would be appropriate to submit the codes to CPT Editorial Panel for the following revisions:

- 1) To develop distinct codes for ascending aortic repair for dissection and ascending aortic repair for other ascending aortic disease such as aneurysms and congenital anomalies. The specialties feel that there is a sufficient difference in the work associated with these procedures and now there is sufficient volume to allow for more accurate capture of the work and outcomes data for these distinct patient populations, which was not the case when the code was first developed;

- 2) Revise the descriptor for the transverse arch code, 33870 to further clarify the difference in work between that code and the new add-on code 33X01;
- 3) Revise the guidelines to provide additional instructions on the appropriate use of these codes. The specialty societies submitted a new coding proposal for consideration at the May 2018 CPT Editorial Panel meeting for CPT 2020.

Although the RUC rescinded their interim RVW recommendation for CPT code 33X01 following the April 2018 RUC meeting due to the societies' recommendation to submit this family of services to the CPT Editorial Panel, STS encourages CMS to consider using the work RVU of 19.74 as an interim value until the code can be re-surveyed and reviewed by the RUC. This will allow physicians to be paid for the service in 2019, decreasing the burden of reporting a carrier-priced service to both the carriers and the providers.

Evaluation & Management (E/M) Visits

Providing Choices in Documentation – Medical Decision-Making, Time, or Current Framework

STS strongly supports the “Patients Over Paperwork” initiative. We appreciate that CMS understands the administrative burden attributable to the current documentation guidelines for the new and established outpatient evaluation and management (E/M) service codes (99201-99215) and are supportive of CMS in addressing these issues to enable physicians to devote more time to patient care. CMS proposed to establish a single payment rate under the PFS for new patient office and outpatient E/M visit codes 99202 through 99205 with a work RVU of 1.90 and a single set of RVUs for established patient E/M visit codes 99212 through 99215 with a work RVU of 1.22. CMS proposes to apply a minimum documentation standard under which practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam, and medical decision-making (“MDM”). CMS anticipates that physicians will continue to provide documentation that is consistent with the level of care furnished for clinical, legal, operational, or other purposes and that practitioners would still report the level of visit (1 through 5) they believe they furnished. However, CMS proposed to allow practitioners to choose either MDM or time, (regardless of the amount of counseling and/or care coordination furnished in a face-to-face encounter) as a basis to determine the appropriate level of E/M office visit to report as an alternative to the current framework specified under the 1995 or 1997 guidelines. To reduce the documentation burden, CMS proposes that practitioners would not be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary for new and established patients. For established patients, practitioners can focus their documentation on what has changed since the last visit or on pertinent items that have not changed. In addition to the single payment rates and the revised documentation recommendations, CMS included a number of policy changes to implement as part of this proposal. Specifically, CMS must create three new add-on codes, make changes to the multiple procedure payment reduction (MPPR) policy, make adaptations to practice expense (PE), and create new specialty-specific E/M codes.

STS has concerns with the E/M payment proposal and believes that CMS can implement the changes to reduce physicians' documentation burden independent of the proposed payment and policy changes. STS urges CMS to **withdraw all of its payment proposals and work closely** with the American Medical Association (AMA) CPT/RUC Workgroup on E/M, the specialty societies and other stakeholders to analyze the E/M coding and payment issues and provide concrete solutions for implementation in the 2020 Medicare Physician Fee Schedule.

STS supports The Patient-Centered Evaluation and Management Services Coalition in proposing that CMS finalize the following changes to documentation requirements while retaining the existing five level coding and payment structure:

1. Allow physicians the option to document visits based solely on the level of medical decision making or the face-to-face time of the visit as an alternative to the current guidelines.
2. If physicians choose to continue using the current guidelines, limit required documentation of the patient's history to the interval history since the previous visit (for established patients).
3. Eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient.
4. Eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty.
5. Remove the need to justify providing a home visit instead of an office visit.
6. Eliminate the requirement that teaching physicians have to enter a separate note in the medical record.

STS agrees that the 1995 and 1997 E/M documentation guidelines are no longer applicable to current practice. EHRs have allowed for easier access to patient information but increased compliance and auditing concerns have resulted in physicians cutting and pasting large volumes of data into the patient record, most of which is not relevant to the specific patient encounter. The inclusion of extraneous data makes it difficult to identify the medical decision-making information related to that visit and isolate the information that supports selection of the code level. The inability to easily identify relevant information for future encounters can lead to medical errors, patient safety issues, and physician burnout.

STS strongly supports CMS' proposal to reduce administrative burden by offering physicians the option to use MDM alone to document for the level of E/M service provided. MDM is fundamental in accounting for the medical complexity of patients, especially for surgeons determining which patients may or may not require surgery. Two of the most important factors for MDM are the review of data and the table of risk. The evaluation of diagnostic tests including imaging has become more complicated. The amount and complexity of the data that is reviewed by the treating physician has increased significantly for many specialties and plays a more important role in MDM than it had previously. The table of risk defines tiers of problems, medical decisions, and management in terms of minimal, low, moderate, and high levels of risk. Continuing to capture the amount and complexity of data and using the table of risk to identify the medical complexity of patients provides a reasonable approach to minimize documentation while maintaining documentation to support the levels of E/M code reported and allowing CMS to continue to audit E/M claims.

Although we are supportive of the proposal, we acknowledge that there are limitations to the use of time alone as a method of documentation. In some cases, time can be a good indicator of the complexity of the visit. However, face-to-face time alone does not capture the intensity or the advance work such as gathering and reviewing data, images, reports, and outside system information for more complex patient interactions. Currently the only data available for time-based documentation for an E/M visits are the typical times for the CPT codes, which represent estimates of time, not measurements. In the proposed rule, it is unclear how the time required for office/outpatient E/M visits would interact with the proposed

new add-on codes and proposed use of the prolonged services codes. It is also unclear how the time required for office/outpatient E/M visits would interact with the proposed new add-on codes and proposed use of the prolonged services codes. We agree that if a physician were to use time to document an E/M and also use the prolonged services code, then the physician should document that the typical time for the base or “companion” visit is exceeded by the amount required to report the prolonged services code. STS does not support the use of time alone as a method of documentation without additional clarification on the time needed for reimbursement of each E/M code given the various approaches that CMS is contemplating, and the varying implications related to each approach.

We are grateful that CMS has proposed to eliminate the requirement for practitioners to re-document information that has already been documented in the patient’s record by practice staff or by the patient for new and established patients and to allow practitioners to focus documentation on what has changed since the last visit or on pertinent items that have not changed for established patients. Data recoded in EHRs allows for access to patient information related to the past medical history, allergies, medications, social history, and family history eliminating the need to re-document this information. Documentation of this information solely for the purpose of meeting documentation requirements is unnecessary for patient care and adds to the complexity of the medical record. Physicians should be able to focus on capturing the data that is necessary to the current disease process and those issues that are relevant to the patient’s treatment. These factors may vary by specialty and/or by the reason for an encounter. The overall state of fitness of a patient is important (physical exam), however the actual exam that is necessary for a physician to perform to evaluate the problem that they are addressing should be relative to the specialty and again may vary based on the reason for the encounter. We encourage the Agency to reconsider their expectation for physicians to conduct elements of history and exam to conform to the principles of the 1995 and 1997 documentation guidelines. Instead CMS should allow physicians to document only the clinically relevant aspects of the history and physical exam related to the current disease process and treatment of the patient.

STS does not support the collapse of the work RVU values into a single payment rate under the PFS to pay for new and established E/M visits billed using the current CPT codes for levels 2 through 5. This will have an extremely negative impact on specialties that predominantly bill level 4 and 5 services and positively impacts specialties that bill mostly level 2 and 3 services. The single-level payment amounts were determined by (1) weight averaging the work RVUs based on specialty utilization for levels 2-5 and (2) establishing a new E/M practice expense pool. While the payment amounts are a calculation of several values that were resource-based, the calculated values are not resource-based. The proposal may also have a negative impact on patient care by disincentivizing physicians to treat the sickest patients because they will no longer be reimbursed for the additional time and resources required by these patients. In addition to the concerns outlined above, the additional policy changes proposed by CMS in order to avoid significant payment cuts (and bonuses) to some specialties are also problematic.

One of the proposed policy changes that is of significant concern is the proposal to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day. CMS cites concerns about overlapping resource costs that are not accounted for when a standalone E/M visit occurs on the same day as a global procedure. However, this is an issue that both the AMA/RUC and CMS have already identified and reviewed through a screen of potentially misvalued codes which resulted in the review of a number of codes and removal of overlapping time, supplies, and equipment. Although not clear in the rule, it appears that it is CMS’ intent to add office/outpatient E/M codes 99201-99215 to the MPPR list by changing the payment indicator to “2” instead of using modifiers to implement this policy. The rule indicates that the MPPR reduction would be applied to separately identifiable E/M visits currently identified on the claim by an appended modifier -25. However, CMS does not propose to limit the reduction to only those procedures with a 0-

day global; as we understand it, the reduction would be tied to all 0, 10, and 90-day global codes. The existing MPPR policy recognizes the efficiencies gained (i.e., evaluation, positioning, scrub/dress/wait, skin-to-skin, postop through recovery) when two or more procedures are performed during the same encounter. It is important to recognize that the components of work for procedures is not the same as the components of work for discreet E/M services. The expansion of the MPPR policy to include office/outpatient E/M codes 99201-99215 would result in additional, unjustified reductions in reimbursement because the overlap in physician work and practice expense has already been accounted for in the valuation of these services. The policy could potentially impact patient care, requiring scheduling of E/M visits and procedures on separate dates to be able to recoup resource costs. CMS proposes to allocate the anticipated 6.7 million RVUs from reduced expenditures under the MPPR policy toward the values for proposed new add-on codes for inherent complexity for certain primary care and specialty care E/M services.

CMS is proposing to create two new HCPCS Level II add-on G-codes that may be billed with the generic E/M code set to adjust payment beyond the typical resources accounted for in the single payment rate for E/M office visits levels 2 through 5. *GPC1X Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)* is intended to more accurately account for the type and intensity of E/M work performed in primary care-focused visits. *GCG0X Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)* is intended to describe the additional resource costs for specialty care that is reported by providers for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches CMS believes are generally reported using the level 4 and level 5 E/M office visit codes rather than procedural coding. STS opposes the implementation of either of these add-on codes because we believe the creation of these codes is an example of differential payment by specialty for the same work. Since the descriptors for the proposed codes state which specialties are allowed to report the code and would vary the PFS payment rate for the E/M visit based on the type of specialty of the physician, they appear to violate the legal prohibition on creating specialty specific payment rates. STS disagrees with the creation of codes that are defined in terms of specialty care instead of patient complexity. Codes that are intended to address “visit complexity” should be tailored to capture the work associated with care for complex patients. Describing a code in terms of specialty care instead of patient complexity will direct use of the code by those specialties toward some patients that are not complex while not allowing the code to be used for some patients who are in fact complex by the remainder of specialties.

In addition to the above policy changes, CMS proposes to create a single practice expense per hour (PE/HR) value for E/M visits based on the average of the PE/HR across all specialties that bill the 10 E/M office visit codes weighted by the volume of those specialties’ allowed E/M services. This new PE/HR will be applied across the 10 E/M office visit codes and all the additional E/M codes that CMS is proposing in the rule. It is not statistically accurate or reasonable to apply current Medicare volume of services by specialty and develop a new specialty category, which assumes that both direct and indirect PE/HR is exactly attributable to individual codes. The calculation of a new specialty PE/HR category results in huge shifts in the Indirect Practice Cost Index (“IPCI”) for a large number of specialties which is further proof that this methodology is not statistically sound. CMS attempted to correct for this through proposed adjustments to the PE/HR calculation; another artificial manipulation of the data. The result is a large unintended effect on specialties given the way indirect PE is allocated. STS does not support the calculation of an E/M PE/HR as a unique specialty.

II. CY 2019 Updates to the Quality Payment Program

Reporting Burden Reduction

CMS is considering further reducing physician reporting burden by linking or otherwise bundling performance categories (e.g., creating sets of multi-category measures that would cut across different performance categories; allowing clinician to report once for credit in all three categories) and/or creating public health priority measure sets. CMS is also considering proposing Merit-based Incentive Payment System (MIPS) public health priority sets across the four performance categories in future rulemaking. The public health priority sets would be built across performance categories and decrease the burden of having to report for separate performance categories as relevant measures and activities are bundled. CMS intends to develop the first few public health priority sets around opioids; blood pressure; diabetes; and general health (healthy habits).

STS believes that physicians who participate in a registry, such as the STS National Database, should be given credit under the performance improvement category. We caution that bundling measures and activities will require significant resources to alter the registry in an ever-changing quality reporting environment.

Group Reporting

CMS has heard an overarching theme to allow a portion of a group practice to report and be assessed as a separate sub-group on measures and activities that are applicable to and reflect the performance of that sub-group. CMS notes there are several operational challenges with implementing a sub-group option, and because of potential gaming opportunities, CMS is not proposing any such policy in this rule. However, it will consider facilitating the use of a sub-group identifier in year four through future rulemaking, as necessary.

As STS has noted in the past, an increasing number of surgeons now practice under larger, multi-specialty and often facility-based groups. Since these groups often opt to participate in federal quality reporting programs at the group practice level (i.e., at the Taxpayer Identification Number level), the individual clinicians in these practices have little autonomy over the selection of measures and reporting mechanisms that are most relevant to their specific specialty and patient population. This arrangement means that cardiothoracic surgeons increasingly do not have the ability to influence their own personal quality scores as the hospitals may elect to report on quality measures that are insignificant or irrelevant to cardiothoracic surgery. As a result, MIPS fails to provide a mechanism by which our specialty, which significantly affects Medicare beneficiaries and is one of the largest cost centers in the Medicare program, can demonstrate value to the Medicare program. **STS continues to strongly urge CMS to address this fundamental problem with the program by creating additional incentives for specialists, including physicians employed by larger or multi-specialty group practices, to come together as more focused entities for purposes of quality reporting and accountability.**

Low Volume Threshold

Currently, to be excluded from MIPS, clinicians and groups must meet one of the following two criterion:

- Have \leq \$90K in Part B allowed charges for covered professional services; OR
- Provide care to \leq 200 Medicare beneficiaries

For 2019, CMS proposes to maintain these thresholds and add a third criterion:

- Provide ≤ 200 covered professional *services* under the Physician Fee Schedule (PFS)

CMS also proposes to allow clinicians to opt-in to the MIPS program if they meet or exceed one or two, but not all, of the low-volume threshold criteria.

STS supports the thresholds as proposed as they offer ongoing protections to clinicians who are not yet capable of making the investment required of this program. We also support providing low-volume clinicians with the opportunity to opt-in to the program if they believe they are ready to begin engaging in the program or would like to prepare before requirements increase in the future years.

General Performance Category Weights in 2019

CMS proposes the following weights for 2019:

- Quality: 45% (down from 50%)
- Cost: 15% (up from 10%)
- Promoting Interoperability: 25% (no change)
- Improvement Activities: 15% (no change)

STS strongly urges CMS to maintain a quality performance category weight of 50 percent and a cost performance category weight of 10 percent. The set of cost measures proposed for use in CY 2019 are in need of refinement or are under-tested (see additional comments in the cost category section below). Additionally, clinicians have far more direct control over quality measures than they do over the current set of cost measures. The Bipartisan Budget Act of 2018 extended CMS' flexibility to count cost measures at between 10 percent and 30 percent of the total score for an additional three years. We believe CMS should take full advantage of this opportunity and maintain the cost category weight at 10 percent.

Quality Performance Category

MIPS Performance Period

CMS proposes to maintain a 12-month minimum performance period for the quality performance category.

STS continues to oppose the CMS policy of requiring a 12-month performance period for both quality and cost data. We urge CMS to adopt a 90-day continuous reporting period for the quality and cost categories of MIPS, which would align with the improvement activities performance category and Promoting Interoperability performance categories of MIPS. CMS notes numerous times throughout the proposed rule that its goal is to minimize the complexity of MIPS program. Requiring two different performance periods in Year 3 only adds complexity to an already confusing program. The 12-month performance period also fails to account for ongoing delays in the release of quality measure specifications and other technical guidance that is critical for participation.

Reporting Across Multiple Mechanisms

For CY 2019, CMS proposes to score individual eligible clinicians on quality measure data submitted across multiple collection types (e.g., via claims and registry). In the initial years of the program, STS supported giving clinicians as much flexibility as possible to meaningfully engage in and satisfy the

requirements of this program. **However, over the longer term, we caution against policies that add to the complexity of the program and divert CMS resources away from more meaningful analytics.**

Data Completeness

CMS does not propose any changes to the previously finalized data completeness threshold that requires those using claims to report on 60 percent of Medicare Part B patients for the performance period and those using QCDRs, qualified registries, and electronic health records (EHRs) to report on 60 percent of patients across all payers for the performance period. However, **STS continues to urge CMS to consider returning to the 50 percent data completeness threshold for QCDRs, qualified registries, EHRs and claims-based data submissions.** This lower threshold is particularly important in light of the proposal to extend the quality performance period to 12 months. **Ideally, we support a 90-day minimum performance period paired with a 50 percent data completeness threshold to account for the ongoing and numerous changes that CMS continues to make in regards to reporting requirements and available measure sets.** While we believe it is reasonable to gradually increase the data completeness threshold over time in order to meet the goals of the MIPS program, we do not believe this bar should be raised until CMS adopts more consistent policies and maintains consistent measure sets from year-to-year.

MIPS Clinical Quality Measures

Listed below are our comments on specific measures proposed for the Thoracic Surgery Measures Set for 2019:

- **#43: CABG: Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** This measure is being proposed for immediate removal from MIPS because it is highly topped out at 99 percent. **We strongly oppose the removal of this measure; in particular, since IMA use is so important to long-term graft patency. We fear that if CMS removes this life-saving measure from MIPS, there will be little incentive for clinicians to report it and thus, a natural tendency for performance to slip without anyone's knowledge. In general, we oppose the proposal to modify the existing topped-out measure policy to allow for the immediate removal of highly topped out measures.**
- **#236: Controlling High Blood Pressure.** This measure is being proposed for removal from the Thoracic Surgery Specialty Set. **STS supports this decision as blood pressure control is appropriately managed by care team members other than the cardiothoracic surgeon.**
- **#441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** This measure is included in the Thoracic Surgery Specialty Set in CY 2018, but is not listed as part of the set for CY 2019 nor is it listed as a measure being proposed for removal from the set. CMS proposes to include this measure in the Cardiology Specialty Set for 2019, which indicates that the agency intends to maintain the measure in MIPS for 2019. **We request that CMS clarify whether it is proposing to remove this measure from the Thoracic Surgery Specialty Set for CY 2019. STS supports the removal of this measure from this set since not all of the four goals reflected in the measure are appropriate for acute surgical patients.**
- **# 317: Screening for High Blood Pressure and Follow-Up Documented:** **STS does not believe this measure is appropriate for the Thoracic Surgery Specialty Set and requests its removal for CY 2019. Blood pressure management is outside of the scope of practice of cardiothoracic surgeons.**

- **#358: Patient-Centered Surgical Risk Assessment and Communication: STS believes this is an important measure to enhance communication and shared decision making, provided the assessment tool is based on published risk models.**

Despite our February 2018 request for CMS to correct this issue, the following measures in the Thoracic Surgery Specialty Set are still inaccurately attributed to the *American Thoracic Society*. We request that CMS clarify that the steward of these measures is the *Society of Thoracic Surgeons*:

- #164: CABG: Prolonged Intubation
- #165: CABG: Deep Sternal Wound Infection Rate
- #166: CABG: Stroke
- #167: CABG: PostOp Renal Failure

Topped Out Measures

During the CY 2018 rulemaking, CMS finalized a 4-year timeline to identify and potentially remove topped out measures. After a measure has been identified as topped out for three consecutive years through the benchmarks, CMS may propose to remove the measure through notice and comment rulemaking. CMS also finalized a 7-point cap to be applied to measures identified as topped out in the published benchmarks for two consecutive years. The final determination of which measure benchmarks are subject to the topped out cap in CY 2019 would not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

In this rule, CMS proposes to change its existing policy so that once a measure has reached an extremely topped out status (e.g., a measure with an average mean performance within the 98th to 100th percentile range), it may propose the measure for removal in the next rulemaking cycle. CMS states that the removal will occur regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. CMS is concerned that topped out non-high priority process measures require data collection burden without added value for eligible clinicians and groups participating in MIPS. CMS would consider retaining the measure if there are compelling reasons as to why it should not be removed (e.g., if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to CMS).

In general, STS strongly opposes the removal of measures that are topped out, including measures that are highly topped out. Without certain commonly used measures, we fear quality patient care will be undermined. Certain measures, including #21: Perioperative Care: Selection of Prophylactic Antibiotic - First OR Second Generation Cephalosporin and #43: CABG: Use of IMA in Patients with Isolated CABG Surgery, are critical for tracking important processes of care, identifying patient outcomes, and ensuring the maintenance of high quality care. As the American College of Surgeons has pointed out, pilots are still required to conduct a pre-flight checklist prior to every flight departure despite performance on this metric being topped out according to CMS' definition. Medical care is complex and quality measure reporting across and within medical specialties is still variable. As such, it is critical that CMS continue to incentivize the use of these measures to ensure they capture broader populations of clinicians and their patients and that they continue to track key processes and outcomes over the long term.

STS strongly believes that measures deemed as highly topped out should not automatically initiate removal from the program, particularly in the early years of MIPS. MIPS quality measure benchmarks are still largely based on historic Physician Quality Reporting System (PQRS) data. Quality reporting requirements and participation incentives have changed substantially over the past few years as clinicians shifted from PQRS to MIPS. It is unfair to make determinations about topped out status based on such inconsistent data. Furthermore, most measures that are currently topped out have been deemed by consensus setting organizations as meeting certain minimum standards related to reliability, validity, and feasibility. Removing these measures due to topped out status, alone, would ignore these other valuable attributes and discount the approval of these standards setting organizations.

Nevertheless, we do believe it is appropriate, once CMS has accrued more MIPS data, for the agency to cap the number of points that a topped out (or highly topped out) measure could earn. As long as this is done through a transparent process with an opportunity for notice and comment, this could balance the need for measures to remain in the program with CMS' concerns that clinicians may be choosing topped out measures as a way to maximize performance scores.

Additionally, we urge CMS to notify measure owners and MIPS eligible clinicians as early as possible that measures are topped out so that they have sufficient time to develop alternative measures and reporting strategies.

Cost Performance Category

CMS proposes to retain the Total Per Capita Costs measure and the Medicare Spending Per Beneficiary (MSPB) measure for this category. **We continue to have concerns with the relevance and appropriateness of these measures for clinician level accountability.** Most clinicians still lack a clear understanding of these measures and question whether the measures capture costs over which they have direct control. For the MSPB measure, in particular, the recent CMS decision to convene a Technical Expert Panel to assist with the refinement of the measure demonstrates that there are issues with the measure that must be fixed before it can be used for accurate clinician-level cost evaluations.

In regards to the Episode-Based Cost Measures, STS believes these measures are a step in the right direction and appreciates the transparent and inclusive process under which they were developed. However, the field-testing period was brief and rushed which led to confusion and prevented clinicians from providing meaningful feedback. Furthermore, the 2017 MIPS Feedback Reports only included general performance scores related to cost measures. CMS did not include any drill-down data to allow clinicians to more fully understand why they were being attributed certain patients and why they were being scored a certain way. The episode-based cost measures should not be used for purposes of scoring the MIPS cost category until clinicians are first given the opportunity to review more detailed confidential feedback under a more reasonable timeline.

Promoting Interoperability

Whereas clinicians may currently use either 2014 or 2015 Edition Certified EHR Technology (CEHRT) (or a combination of both) to satisfy the requirements of this category, for CY 2019, CMS proposes to require clinicians to move to 2015 Edition CEHRT. STS recognizes that the 2015 Edition offers enhanced functionalities to better promote interoperability and that many clinicians have already transitioned to 2015 CEHRT. However, for those who have not, they continue to face financial or other logistical reasons that prevent them from easily upgrading. CMS also notes that one of the major improvements of the 2015 Edition CEHRT is the Application Programming Interface (API) functionality. However, few, if any, APIs exist today that are relevant to surgeons and their patients. As a result, there is less of an incentive

for surgical specialists to invest in upgrades at this time. **We urge CMS, at least in the initial years of the program, to continue to offer flexibility for clinicians who find it infeasible to upgrade their systems in time for the CY 2019 MIPS performance periods.**

CMS proposes to reduce the number of measures and to simplify the overall scoring methodology of the performance improvement (PI) category. CMS would eliminate the base, performance, and bonus scoring structure and instead use a single performance-based methodology, rather than the previous threshold approach. **While we appreciate and support this more simplified approach, we urge CMS to provide more flexibility in this category. The proposed scoring methodology still relies on an all-or-nothing approach where a clinician must report something for every single measure to receive a score in this category. Instead, clinicians should be able to earn a certain amount of points by reporting on any mix of measures that is most relevant to their practice.**

CMS also proposes to add two new opioid-focused measures to the PI Category, which would be voluntary in 2019 and required in 2020: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. While we fully appreciate the intent of these two measures, we believe there are too many ongoing challenges related to e-prescribing of Schedule II opioid prescriptions and the ability of EHRs to easily query a PDMP. State laws still vary widely, as does user experience with PDMPs across the country. **If CMS adopts these measures, we recommend that they remain voluntary for the next two years.**

In this section of the rule, CMS also notes its intent to propose in the future to remove the Public Health and Clinical Data Exchange objective and measures from the PI category no later than CY 2022. The agency seeks public comment on this decision and other policy levers to encourage reporting to public health and clinical data registries. **STS urges CMS to retain this objective and its measures as a necessary incentive for clinicians and, perhaps more urgently, EHR vendors to share data electronically with public health entities and clinical data registries. While many clinicians may continue to share data with clinical data registries even if this objective were removed, this objective provides a necessary incentive for EHR vendors to communicate data seamlessly with registries.**

Finally, STS eagerly awaits the implementation of the interoperability portions of the 21st Century Cures Act. In particular, we are eager to work with the relevant agencies on the promoting interoperability between and among EHRs and clinician-led clinical data registries as defined under Section 4005 of the 21st Cures Act.

Qualified Clinical Data Registries (QCDR)

Measure Approval Process

In the CY 2018 QPP proposed rule, CMS requested information on a multiyear approval process for QCDR measure approvals. While CMS did not address this in the CY 2019 proposed rule, STS reiterates our position that a two-year timeframe for measure approvals would be acceptable. However, **we urge CMS to make exception to this proposal to allow a QCDR to replace a measure if deems necessary.**

Proposed Update to the Definition of a QCDR

In the CY 2019 proposed rule, CMS is proposing to update the definition of a Qualified Clinical Data Registry (QCDR) to require an approved QCDR to have clinical expertise in medicine and quality measure development.

STS strongly supports the revised definition. The STS National Database (the Database), currently approved by the CMS as a QCDR, was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The Database has four components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery as well as mechanical circulatory support via the Intermacs Database. The National Database is guided by the clinical experts in these four components and uphold the fundamental principle 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.

QCDRs Seeking Permission from Another QCDR To Use an Existing, Approved QCDR Measure

CMS asserts that following the CY 2018 policy that allows QCDR vendors to seek permission from another QCDR to use an existing measure has created a financial burden for QCDRs as many QCDRs charge a fee for use of their measure. In response to this assertion, CMS is proposing that as a condition of being an approved QCDR measure, the QCDR measure owner will be required to make the measure generally available to other QCDRs without a fee.

STS joins other specialty societies in strongly opposing this proposal. Development and approval of QCDR measures is time consuming and resource intensive. Offering our measures to other QCDRs without a fee undermines the level of work and resources used to develop these important quality measures. STS urges CMS to reconsider its CY 2019 and allow QCDRs to enforce their own measure ownership rights for the measures that they develop.

MIPS Scoring and Payment Methodology

The Bipartisan Budget Act of 2018 gives CMS flexibility in establishing the MIPS performance threshold for three additional years (program years 3, 4, and 5) to ensure a gradual and incremental transition to the sixth year of the program, when the performance threshold must be based on the mean or median of final scores from a prior period. Using this authority, CMS proposes to set the performance threshold at 30 points (up from 15 points) and the exceptional performance threshold at 80 points (up from 70) for 2019.

STS is deeply concerned by the proposal to double the performance threshold in CY 2019 given the ongoing complexity of the program, the proposal to remove a substantial number of quality measures from the program, and insufficient historical MIPS data on which to set benchmarks and to determine the feasibility of the current performance threshold. We urge CMS to more gradually increase the performance threshold as clinicians continue to adjust to this new and confusing program and until there is more robust data on which to make determinations about appropriate performance thresholds.

Facility-Based Scoring

CMS proposes to provide an option to use facility-based Quality and Cost performance measures and scores for certain facility-based clinicians under MIPS starting in 2019. Clinicians or groups who meet this definition could potentially be scored under the MIPS Quality and Cost categories based on their facility's Hospital Value-Based Purchasing (VBP) Program (VBP) score. STS appreciates that CMS proposes to preserve this proposal and recognizes the individual and group reporting mechanisms and challenges that facility-based clinicians currently face in regards to engaging in MIPS in a meaningful manner. While these challenges are sometimes due to lack of relevant measures, they are more often due

to the current limited structure of MIPS participation options. Although the group practice reporting option is intended to ease reporting burden, it often discourages the reporting of specialty specific measures.

In addition we note that the group practice reporting option does not always incentivize true team-based approaches to care that are foundational to raising the bar on quality. Individual physicians often have little to no control over their groups' measure selections, reporting mechanisms, and overall participation decisions. In fact, CMS seems to be cutting back on VBP measures-- particularly specialty, procedure and condition-specific ones. Thus, individual specialists have no way to demonstrate the value of their own care. The proposal to tie facility-based clinicians' MIPS scores to the Hospital VBP Program provides these clinicians with an alternative participation option, but still does not provide facility-based clinicians with a way to demonstrate their unique value. This is especially true as the VBP program moves away from episode-specific measures and more towards the use of broader, hospital-wide measures (e.g. all-cause mortality, all-cause readmissions, Medicare Spending Per Beneficiary).

STS encourages CMS to adopt policies that further encourage specialists to engage in MIPS more meaningfully, particularly through the use of QCDRs. QCDRs provide a valuable and unique source of specialty-specific quality data that is not collected elsewhere. CMS has stated that it will accept the higher of the two reported quality scores. While it is not likely that an individual's quality score will be substantially higher than their facility-reported score, CMS should consider the fact that having baseline quality data across medical specialties may be important to the future of a quality-based payment program's entire value equation. Without incentives for specialist to report practice-specific quality metrics, CMS is setting its quality improvement efforts back and undermining previous years of progress.

We also see great potential value in the "virtual groups" concept, which would give individuals the flexibility to determine if they want to be evaluated as part of a unique group of clinicians that might not necessarily align with their billing TIN, and to determine which other individuals best represent their "care team."

Physician Compare

In the CY 2018 QPP final rule, CMS finalized a policy to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category. The policy calls on CMS to periodically post aggregate information on the MIPS program, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years. CMS clarifies that although all information submitted under MIPS is technically available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database. These data must first meet CMS' public reporting standards.

In this rule, CMS proposes to not publicly report first year quality and cost measures for the first two years the measure is in use to help clinicians and groups gain feedback on these measures. **STS strongly supports this proposal since it takes multiple years for new measures to accrue data that can be used for accountability purposes.**

CMS also proposes to add star ratings for QCDR measures using the agency's adopted Achievable Benchmark of Care (ABC™) methodology beginning with performance year two. **In general, STS opposes the use of the ABC methodology for purposes of public reporting since it relies on a benchmarking methodology that is different from what CMS uses for purposes of MIPS scoring**

and payment. This is not only confusing, but results in inconsistent performance assessments depending on the purpose of the program. We strongly oppose the use of the ABC methodology for QCDR data, specifically, since it differs from STS' own methodology for rating performance, which could further confuse and mislead patients.

III. Requests for Information

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the proposed rule, CMS states, “in order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under section 2718(e) of the Public Health Service Act.” The requirement that hospitals publish a list of standard charges for items and services is just one of the tools employed in Section 2718(e) of the Public Health Service Act to ensure that consumers receive value for their premium payments. Yet it has also become increasingly clear that CMS has struggled to adequately define value in health care. To better facilitate value transparency, the proposed rule attempts to address problems with the agency’s ability to define and make publicly available information relevant to the cost side of the value equation: namely a list of standard hospital charges for items and services. While the comments that follow address how CMS can further facilitate cost or “price” transparency, we would note that CMS has also struggled with publicly communicating the quality side of the equation in a way that can be useful to patients, even when reliable data exists.

While defining quality measures for Medicare providers under the various physician fee schedule payment models has been a challenge, CMS continues its reluctance to rely on quality measures developed by medical specialties that have been demonstrated to improve quality. STS National Database™ was established in 1989 as an initiative for quality assessment, quality improvement, and patient safety among cardiothoracic surgeons. The Database has four components—STS Adult Cardiac Surgery Database, STS General Thoracic Surgery Database, STS Congenital Heart Surgery Database, and STS Intermacs Database (mechanical circulatory support). The fundamental principle underlying 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 create the most powerful mechanism for change and improvement in the practice of cardiothoracic surgery for the benefit of patients. In fact, published studies indicate that quality of care has improved as a result of research and feedback from STS National Database.^{1 2 3 4 5 6} STS National Database has facilitated advancements in many aspects of health care policy, including NQF approval of 34 quality measures, public reporting of

¹ ElBardissi AW, Aranki SF, Sheng S, et al. Trends in Isolated Coronary Bypass Grafting: An Analysis of The Society of Thoracic Surgeons Adult Cardiac Surgery Database. *J Thorac Cardiovasc Surg* 2012;143:273-281.

² Speir AM, Rich JB, Crosby IK, et al. Regional Collaboration as a Model for Fostering Accountability and Transforming Health Care. *Semin Thorac Cardiovasc Surg* 2009;21:12-19.

³ LaPar DJ, Speir AM, Crosby, IK, et al. Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs. *Ann Thorac Surg* 2014;98:527–533.

⁴ Osnabrugge RL, Speir AM, Head SJ, et al. Cost, Quality, and Value in Coronary Artery Bypass Grafting. *J Thorac Cardiovasc Surg* 2014;148:2729-2735.

⁵ LaPar DJ, Rich JB, Isbell JM, et al. Preoperative Renal Function Predicts Hospital Costs and Length of Stay in Coronary Artery Bypass Grafting. *Ann Thorac Surg* 2016;101:606-612.

⁶ LaPar, DJ, Speir AM, Crosby IK, et al. Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs. *Ann Thorac Surg* 2014;98:527-533.

health care quality measures in collaboration with Consumer Reports, facilitation of medical technology approval and coverage decisions, and fostering cost savings that help cardiothoracic surgeons find the most efficient and effective way to treat patients. However, CMS has been reluctant to rely on these tried and true measures of quality, opting for measures that are far less meaningful to patients and to surgeons who are trying to improve the care they provide.

Recent reports indicate a variety of problems with the accuracy and reliability of hospital star ratings that CMS has been publishing since 2016.⁷ These star ratings are intended to help patients' evaluate hospitals so that they can determine where they are likely to get the highest quality care. However, due to the issues recently identified, CMS decided to postpone the July release of its hospital star ratings data. Here again, with respect to cardiothoracic surgery, CMS is attempting to recreate the wheel. As a national leader in health care transparency and accountability, STS believes that the public has a right to know the quality of surgical outcomes⁸. As a result, the Society established STS Public Reporting initiative in 2010. This program allows participants in STS National Database to voluntarily report their surgical outcomes on STS website, the Consumer Reports website, or both. These star ratings were even published in Consumer Reports.

In the proposed rule, CMS further states that “we are also considering other potential actions that would be appropriate, either under the authority of section 2718(e) of the Public Health Services Act *or under another authority*” (emphasis added). CMS also asks “What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interacts with these data?”

The Society is in agreement with CMS that the most valuable tool for patients who are interested in making proactive choices about their health care is value transparency. Fortunately, STS National Database already provides for quality transparency through STS Public Reporting online. If CMS were to adequately implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), we would have access to Medicare claims data, or the cost denominator of the value equation. Unfortunately, the programs CMS has offered to implement that section of statute are not working.

Section 105(b) of MACRA 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 risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety. CMS initially decided not to issue rulemaking on this section of the law based on its assertion that QCDRs currently can request Medicare claims data through the ResDAC data request process. This position ignored the fact that Section 105(b) is intended to provide QCDRs with access to Medicare data for quality improvement purposes, not just clinical research, and that the broad and continuous access needed for quality improvement purposes is fundamentally different than the access to Medicare data for research purposes provided by ResDAC. In subsequent rulemaking, CMS decided to treat QCDRs as “quasi-qualified entities” for purposes of obtaining access to Medicare claims data for quality improvement, but maintained that QCDRs should use the ResDAC application process for research

⁷ Castellucci, M. (2018, June 15). *CMS Star Rating System has been Wrong for Two Years, Health System Finds*. Retrieved from Modern Healthcare: http://www.modernhealthcare.com/article/20180615/TRANSFORMATION01/180619933?utm_source=modernhealthcare&utm_medium=email&utm_content=20180615-TRANSFORMATION01-180619933&utm_campaign=am

⁸ The Society of Thoracic Surgeons. STS Public Reporting Online. <https://publicreporting.sts.org>. Accessed March 20, 2018.

requests. While we appreciate CMS's effort to provide QCDRs with an alternative means of accessing Medicare data, treating QCDRs as quasi-qualified entities does not allow the type of access contemplated by Section 105(b) of MACRA.

To perform data analysis for quality improvement purposes and patient safety, QCDRs require long-term and continuous access to large Medicare datasets so that they can better track clinical outcomes longitudinally. In drafting Section 105(b) of MACRA, Congress was aware of this need and, as such, specifically directed CMS to provide QCDRs with Medicare claims data. Qualified entity status lasts only for 3 years and continued participation in the program requires re-application by submitting documentation of any changes to the original application. If the re-application is denied, CMS will terminate its relationship with the qualified entity. In addition, Medicare fee-for-service files are released quarterly on an approximate 5.5 month lag. Qualified entities must pay for each set of data they receive, which can become cost prohibitive over time.

While the qualified entity regulations contain some provisions that may help expand QCDRs' access to claims data, the onerous requirements and lengthy application process required to become a qualified or quasi-qualified entity stand as a substantial barrier for QCDRs to gain the data access mandated by Section 105(b). The statute was intended to recognize the QCDR certification process, which itself is long and arduous, as sufficient demonstration of fitness for receiving claims data from CMS. QCDRs maintain the strictest of privacy standards, among other things, and are proven to be legitimate and secure repositories of patient information.

The quasi-qualified entity program covers only the "quality improvement" portion of a QCDR's access to claims data. If the same QCDR wanted to facilitate research combining cost and claims information, that QCDR would have to submit a separate application to ResDAC. In fact, if the QCDR already had the claims data in question through the quasi-qualified entity program, it would still need to apply and pay ResDAC for the same data. The ResDAC application is duplicative, time-consuming, and costly, with a significant lag between application approval and delivery of data.

At the same time, every new payment model released by CMS and the Center for Medicare and Medicaid Innovation includes a provision that hospitals and qualified participants should be able to access their own claims information and any additional information deemed necessary by the participant. Clearly, CMS understands the value of price transparency in health care, yet it is failing to implement statute that speaks to that purpose.

If CMS is truly interested in using its existing authority to provide information on the value of health care to the Medicare population, it will take another look at how it is implementing Section 105(b) of MACRA. Absent that ideal scenario, CMS should provide claims data to the providers with a straightforward breakdown of inpatient costs, provider costs, post-acute care costs, home health costs, readmission rates, and costs. Given these data and local or regional (not necessarily national) benchmarks, providers (and patients) will have an idea where care can improve and where there are opportunities to improve efficiency. If benchmark prices from big data are created, the methodology employed should be clear and include relevant stakeholders in the development.

The Society of Thoracic Surgeons appreciates the opportunity to provide our comments on proposed changes to the Calendar Year 2018. STS appreciates the opportunity to provide feedback on proposed policies related to the CY 2019 physician fee schedule, the request for information on price transparency, and the implementation of updates to the Quality Payment Program (QPP). We look forward to working with CMS as it continues to implement these policies. Please contact Courtney Yohe, Director of

September 10, 2018
Administrator Verma
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Government Relations at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,

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

Keith S. Naunheim, MD
President