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Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1631-P - Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Mr. Slavitt:

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for calendar year (CY) 2016 proposed rule that was published in the Federal Register on July 15, 2015.

Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

II. Provisions of the Proposed Rule for PFS

A. Determination of Practice Expense (PE) Relative Value Units (RVUs)

2.c.(6)(c) Create the Indirect Cost PE RVUs

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with technical components (TCs) and professional components (PCs), the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

STS agrees with the CMS proposal to utilize an average of the three most recent years of available claims data to determine the practice expense (PE) specialty mix and help reduce fluctuation from year to year. The dominant specialty specific overrides used for the malpractice (MP) RVU will also need

to be used for the PE calculations to ensure the correct specialty or specialty mix is assigned for each code of the PE RVU for low volume specialties where the majority of services are either not performed or rarely performed in the Medicare population.

c. Changes to Direct PE Inputs for Specific Services

In general, STS agrees with the American College of Surgeon's (ACS) comments that specialty societies should be afforded the opportunity to request deviations from the standard practice expense (PE) inputs. Finally, we agree that CMS work with the RUC and specialty societies before adjusting the existing times for current codes.

B. Determination of Malpractice Relative Value Units (RVUs)

2. Proposed Annual Update of MP RVUs

STS agrees with the CMS proposal to begin recalculating service-level RVUs based upon the mix of practitioners providing the service annually beginning in 2016. STS encourages CMS to collect professional liability insurance (PLI) premium data on an annual basis as opposed to every five years to ensure accurate PLI payment for every service.

STS also agrees with the CMS proposal to use a three-year average of claims data to determine the specialty mix assigned to each code for the MP RVU. STS agrees that, for low volume specialties and specialties where the majority of services are not performed, or rarely performed in the Medicare population (e.g., pediatrics), CMS will still need to utilize dominant specialty overrides to ensure that the correct MP RVU is applied to each code. We encourage CMS to publish in prior rulemaking each year, the dominant specialty-specific overrides estimated for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service.

STS provided comments on the 2015 Physician Fee Schedule proposed and final rules specifically identifying 34 codes where the MP RVUs were incorrectly assigned. In all 34 codes, the cardiothoracic specialty and subspecialties provide the majority of services. Our concern with the MP RVUs for most of these codes stemmed from the fact that they are low volume Medicare services for which CMS calculated a blended malpractice risk factor. In the final rule, CMS overrode the claims-based dominant specialty for only three of the 34 codes submitted for consideration by STS. 28 of the codes that STS raised questions about were congenital cardiac codes and were among those that were not corrected. By definition, congenital cardiac codes are likely to be low volume in the Medicare population because these surgical procedures are performed predominantly on children and babies.

Addendum B – Relative Value Units and Related Information Used in CY 2016 Proposed Rule shows that the MP RVUs for these 28 codes will be corrected for 2016. We appreciate CMS working with us to correct these issues and request that CMS include the MP RVU corrections, rationale, and methodology related to congenital cardiac services in the Final Rule for CY 2016 to ensure that this error cannot be repeated.

The Table below shows the 28 congenital cardiac codes that will be corrected CY 2016.

CPT Code	Short Descriptor	MP RVU 2015	Fac Total RVU 2015	MP RVU 2016	Fac Total RVU 2016
33471	Valvotomy pulmonary valve	1.59	36.41	5.44	40.33
33606	Anastomosis/artery-aorta	2.18	49.05	7.47	54.41
33611	Repair double ventricle	2.46	54.02	8.43	60.07
33619	Repair single ventricle	3.37	75.27	11.56	80.01
33676	Close mult vsd w/resection	2.55	56.05	8.75	62.33
33677	Cl mult vsd w/rem pul band	2.67	58.24	9.11	64.77
33692	Repair of heart defects	2.51	54.27	8.57	60.40
33737	Revision of heart chamber	1.56	35.70	5.33	39.55
33755	Major vessel shunt	1.56	36.19	5.36	40.06
33762	Major vessel shunt	1.56	35.32	5.36	39.19
33764	Major vessel shunt & graft	1.56	36.19	5.36	38.64
33768	Cavopulmonary shunting	0.55	11.61	1.89	12.16
33770	Repair great vessels defect	2.70	58.69	9.26	65.33
33771	Repair great vessels defect	2.82	60.48	9.63	67.36
33775	Repair great vessels defect	2.29	51.16	7.83	56.78
33776	Repair great vessels defect	2.41	54.06	8.24	59.98
33777	Repair great vessels defect	2.37	52.29	8.11	58.12
33778	Repair great vessels defect	2.96	65.01	10.13	72.27
33779	Repair great vessels defect	3.00	65.54	10.25	71.87
33780	Repair great vessels defect	3.05	65.71	10.41	69.56
33781	Repair great vessels defect	2.98	64.19	10.24	71.54
33783	Nikaidoh proc w/ostia implt	4.50	96.85	15.43	107.89
33786	Repair arterial trunk	2.90	63.06	9.93	66.82
33803	Repair vessel defect	1.39	31.70	4.81	33.55
33813	Repair septal defect	1.49	34.10	5.06	37.74
33822	Revise major vessel	1.23	28.15	4.20	31.15
33840	Remove aorta constriction	1.49	34.07	5.05	37.59
33851	Remove aorta constriction	1.53	35.00	5.21	33.74

In addition to the corrected MP RVUs for the congenital codes, STS has identified three additional low volume codes typically performed by cardiac surgery or thoracic surgery that have anomalous MP RVU values. Unfortunately, two of these codes do not appear to be corrected for 2016. These errors can also be attributed to a misunderstanding of our specialty designation and/or faulty utilization data for low-volume codes.

STS represents the specialty of cardiac surgery, which encompasses adult cardiac surgery, congenital cardiac surgery, and general thoracic surgery, which is surgery on the chest wall, esophagus, lungs, mediastinum, trachea and bronchi. There is only one board certification for cardiac and general thoracic surgery through the American Board of Thoracic Surgery. It is very common for thoracic surgeons to perform both cardiac and general thoracic surgery; however, each surgeon has a designation of either CARDIAC SURGERY or THORACIC SURGERY in the Medicare utilization file. Thus, many obvious cardiac and general thoracic procedures have sizable percentages performed by both "specialty designations."

The malpractice risk factor for both cardiac surgery and general thoracic surgery is naturally very similar. Confusion arises through a failure by CMS to appreciate that "Cardiac Surgery" and "Thoracic Surgery," although separately classified by CMS, actually represent a community of surgical practitioners within a single board-certified specialty that performs "cardiothoracic surgery."

31766 – Carinal reconstruction. Thoracic surgeons perform this low volume, but highly complex, surgical procedure. Of course, because this is a low volume procedure, any misreporting of services would impact the specialty MP RVU. According to the Medicare Utilization File, only five carinal reconstructions were performed in 2013. Thoracic surgeons billed two of the five cases, and cardiac surgeons billed two. The last one was billed by *pulmonary medicine*, which must be a flawed claim, as this code exclusively describes a major thoracic surgical procedure. In the 2014 utilization data, seven procedures were performed, 85.71% by Thoracic Surgery and 14.29% by Cardiac Surgery resulting in 100% performance by cardiothoracic surgery.

Thus for 31766, using the risk factor for either cardiac or thoracic surgery or even a blend of both would be appropriate. For 2016, it appears that the MP RVU has been corrected (2.18 in 2015 to a proposed MP RVU of 6.80 in 2016), however, STS recommends that CMS flag this code for a dominant specialty override using either THORACIC SURGERY or a blend of THORACIC SURGERY and CARDIAC SURGRY to calculate the MP RVU to ensure that the correct specialty mix MP RVU is assigned to the code irrespective of coding errors.

The next two CPT codes demonstrate where faulty utilization data are a major factor in leading to abnormally low PLI.

Code 33420, valvotomy, mitral valve; closed heart, is a low volume cardiac surgical procedure to relieve mitral stenosis. During this procedure, a dilatation device is directly inserted into the *beating heart* through a pursestring suture, and the surgeon's finger is inserted through another pursestring suture. The surgeon manipulates the device across the mitral valve by "feel" and the device opens the fused valve. This is a low volume code with 10 procedures in the Medicare utilization data. Four of these procedures were performed by THORACIC SURGERY, three were performed by CARDIAC SURGERY, two were inexplicably attributed to HEMATOLOGY/ONCOLOGY, and one was billed by GENERAL SURGERY. Similar to the example above, cardiothoracic surgery is the dominant specialty performing the procedure 70% of the time, with the remainder erroneously billed. For 33420, it would be appropriate to assign the malpractice risk factor associated with CARDIAC SURGERY. We would suggest that data

indicating that 20% of 33420 procedures are performed by HEMATOLOGY/ONCOLOGY represent an obvious coding inaccuracy since physicians in these specialists have no training in complex cardiac surgery. STS recommends that the finalized MP RVU values for 33420 be changed to reflect the malpractice risk factor of CARDIAC SURGERY.

32654, thoracoscopy, surgical; with control of traumatic hemorrhage, is a major general thoracic procedure involving a video-assisted thoracic surgery (VATS) approach to control bleeding in the chest due to trauma. CMS has degraded the PLI for this procedure from 22% of the relative value of work (RVW) to 19% of RVW due to utilization by PULMONARY DISEASE (19.72% PLI) and a potpourri of other specialties including CARDIOLOGY. This is not a low volume code by CMS criteria (2013 utilization=244, 2014 utilization=213), but again, ours is the dominant specialty with 52.58% THORACIC SURGERY and 11.27% CARDIAC SURGERY for a total of 63.85% in 2014. The utilization pattern is consistent with inaccurate coding by medical specialties, as this code clearly describes and is valued as a major surgical procedure.

Cardiac and thoracic surgeons performing 32654 should not be penalized for inaccurate coding by other medical specialties that have no training in thoracic surgery, in trauma surgery, or in other surgical means to control traumatic hemorrhage. STS recommends that the finalized MP RVU values for 32654 be changed to reflect the malpractice risk factor of THORACIC SURGERY.

C. Potentially Misvalued Services Under the Physician Fee Schedule

4.c. Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or More

STS agrees with the RUC that CMS should remove the five add-on services (22614, 22840, 22842, 22845 and 33518) from the table titled “Proposed Potentially Misvalued Codes Identified Through High Expenditure by Specialty Screen” (Table 8 in the proposed rule). Since these are all add-on codes to 010-day or 090-day global services, which were excluded from the query to generate this list of high expenditure procedures, the associated add-on services above should also be excluded.

6. Improving the Valuation and Coding of the Global Package

b. Impact of the Medicare Access and CHIP Reauthorization Act of 2015

CMS seeks feedback on a number of issues related to the data collection and valuation of global services. We very much appreciate that CMS plans to seek comments, in addition to the rulemaking process, for developing a proposal for CY 2017 to collect data needed to value surgical services. We urge CMS to utilize any available means to obtain comments including open door forums, town hall meetings with the public, and other avenues. We also urge CMS to allow stakeholders to provide additional written comments on policies that CMS is developing for collecting these data, either in the form of a response to a request for information (RFI), written comments following a town hall, or by some other mechanism.

In general, STS agrees with comments provided separately by the ACS, specifically as they pertain to practice expense, PLI RVUs and overall accuracy of the global package:

- Practice expense: As CMS values the procedure itself, separate from the global code, the agency should incorporate the PE value that is unique to follow up visits in the base or "parent" code. This will prevent an unfair devaluation of the cost of supplies, labor, and equipment that is consumed in caring for the Medicare patient in the post-operative outpatient visits. In addition, there are a number of post-operative services included in 10- and 90-day global codes that cannot be reimbursed using the current separately billable E/M codes. These post-operative services represent real dollar cost outlays by surgeons, both for supplies as well as labor, that are fairly paid for using the existing methodology in the 10- and 90- day global codes, but would be unpaid if surgeons were left to bill for them by using E/M codes. Examples of these services are listed in the Medicare Claims Processing Manual and include items such as: dressing changes; local incision care; removal of operative packing; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters; routine peripheral intravenous lines; nasogastric and rectal tubes; and changes and removal of tracheostomy tubes.

- Professional Liability Insurance: In valuing the individual components of a global service separately, it is important that CMS prevent potential artificial reductions in PLI RVUs for some specialties. We urge CMS not to use a methodology that redistributes the PLI associated with the global period to other specialties. A revised PLI formula should also properly and fairly credit resource-based specialty PLI costs to each specialty proportional to its own unique PLI costs.

- Overall Accuracy: CMS is also interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. With respect to the application of multiple procedure payment reduction policy, we agree with the ACS comment that, continuing to apply the same reduction percentage to the procedure component of the 10- and 90-day global code alone would inappropriately reduce the payment for second and subsequent surgical services.

To collect auditable, objective data that identifies the number and type of visits and other services furnished by the practitioner reporting the procedure code during the current post-operative periods, STS recommends that CMS consider requesting that all physicians report the number of minutes spent for an E/M visit whether or not such services are provided in the postoperative period. For services that occur within the postoperative period, providers could report 99024 with the minutes spent for the visit. This would provide CMS with objective data that would be suitable for audit without adding much complexity for physicians reporting services. By collecting the amount of time spent on all E/M services, CMS would be able to compare the postoperative visit time to an E/M service provided outside of the global period. This would allow analysts to determine if similar time is being spent for stand-alone E/M services and postoperative E/M services and if the visits differ. CMS could use the time criteria established for the E/M visits to determine the level of postoperative services provided for the

postoperative E/M services during the global period.

We encourage CMS to develop a non-payment code similar to 99024 to facilitate the collection of information for other items and services relating to the surgery that are provided during the global period. This unique code could identify services that are furnished but not separately billable after the day of the procedure during the global period. Practitioners would report either the time spent providing the service or reference an existing CPT code if one is available. This "new 99024" code should not be reported for E/M services or services that can be billed with a modifier during the global period. In addition, it should only apply to those additional services or interventions that occur after the day of surgery that cannot otherwise be billed such as removal of a chest tube following aortic valve replacement surgery or removal of an Intra Aortic Balloon Pump for any number of cardiac surgical procedures.

As CMS is aware, it is costly to develop and collect tools for data acquisition. Therefore, we encourage CMS to consider developing new ways of providing additional compensation for data collection. Further, we firmly believe that collection and analysis of these data should be an integral component of the valuation process. STS has a RUC-approved methodology that has been accepted by CMS to value the individual components of the global surgical package. STS methodology utilizes time and intensity data to value the procedure itself (including the pre- and post- time), ventilator duration, ICU length of stay (LOS), and overall hospital length of stay data, as well as an expert panel to determine the number and level of hospital visits for a procedure. In addition, an expert panel is used to determine the number of office visits required for a procedure. STS utilized data from the STS Adult Cardiac Surgery Database to determine, intraservice time, ventilator time, ICU and hospital LOS time.

To determine an appropriate value for the procedure itself, procedure time and procedure intensity are of paramount importance. STS suggests that CMS work with the RUC to determine an accepted intensity survey process and formulaic scale that can be utilized across specialties to accurately determine the intensity for the procedure. Once this intensity measure is established, the surveyed intensity (or intensity scale), the surveyed or database intra-service time, and the pre and post procedure time packages from the RUC can be used to value the procedure itself to ensure that it is properly valued within the global package.

D. Refinement Panel

2. CY 2016 Refinement Panel Proposal

STS has no objection with respect to the CMS proposal to formally discontinue the Refinement Panel. However, given the stated importance of "transparency" in the process of commenting on interim proposed code values and maintaining a fair method of appeal, we would ask that CMS do more than allow subspecialty stakeholders two opportunities for comment. We believe it is critically important to have an appeals process to provide a mechanism of objective, third party review and adjudication. Without such a mechanism, issues such as transparency lose relevance and make CMS the sole arbiter of final code values with no credible avenue of redress for stakeholders.

F. Target for Relative Value Adjustments for Misvalued Services

STS supports the RUC comments and would re-emphasize the following: We encourage CMS to establish a fully transparent process to ensure that stakeholders can independently verify their own specific net-reduction calculations each year. Furthermore, we encourage CMS to publish the exact target reduction number and individual service-level impacts for each year so that the individual stakeholders can fairly and accurately calculate the published reduction.
Finally, we agree with the RUC in that CMS's intention to include advanced care-planning services in its overall target reductions is counter intuitive. The cost of implementing advanced care planning services, as well as payments to other care management services should be managed as "redistribution" from other physician services for CY 2016.

1. Distinguishing "Misvalued Code" Adjustments from Other RVU Adjustments

New technology codes 21811-21813 (rib fracture fixation) should not be included as misvalued codes for net reduction calculations. These three codes were never part of any potentially misvalued consideration and instead are the result of transitioning Category III codes (0245T-0248T) to Category I status per a request by industry stakeholders. We do agree, however, that three other rib fracture treatment codes (21800, 21805, 21810) were identified as potentially misvalued and were submitted for deletion. This action was completely independent of the industry requested Category I status for new technology codes and none of these three deleted Category I codes were referred to the new technology codes. Therefore, codes 21811, 21812 and 21813 should not be included in the list of codes defined as misvalued for the target; however codes 21800, 21805, and 21810 should be included in the list.

G. Phase-in of Significant RVU Reductions

STS disagrees with the proposed phase-in significant decreases in value for specific codes. However, if codes are phased-in as proposed by CMS, the full impact of the reduction should be counted toward the misvalued code target in the first year rather than being spread over the phase in period towards the misvalued code target.

I. Valuation of Specific Codes

Before commenting on codes specific to cardiac and thoracic surgery, STS notes that across a number of specialty areas, CMS proposes work RVU recommendations for a large number of individual codes that are different from the RUC-recommendation. In fact, the CMS proposed work RVU is less and never greater than the RUC recommendation. In arriving at its proposed work RVU, CMS in many cases used mathematical adjustments to physician time ignoring physician survey data, clinical expertise, and magnitude estimation. STS remains concerned with CMS deviation from the RBRVS established principles of code valuation.

6. CY 2016 Valuation of Specific Codes
c. Advance Care Planning Services

We are grateful to CMS for the proposal to reimburse physicians and other providers for advance care planning services. We believe that, by recognizing the value of this conversation, CMS is truly empowering seniors and other Medicare beneficiaries to make decisions about the type of care they receive and when they receive it. We agree with the CMS proposal to change the assigned indicator for the advance care planning codes from an "I" to an "A" to allow for payment of codes 99497 and 99498 for advance care planning. In addition, STS agrees with the proposal to adopt the RUC recommended values (work RVUs, physician time, and direct PE inputs) for these codes. The codes for advance care planning are clearly defined by CPT, and represent work above and beyond an E/M service provided on the same or different day. As such, this work should be compensated. The rationale for the creation of this code was to provide patients with an additional and distinctly different level of service. The added benefit to patients is significant and the physician work associated with providing this service is, likewise, significant. Physician compensation for this additional work would be appropriate. We would also urge CMS to allow surgeons to use these codes. There are many situations where it is necessary for the surgeon to discuss advance care planning with the patient. This may include services prior to performing a surgical procedure, or when the decision is made not to perform surgery. Either action may require advanced care planning services with the surgeon.

d. Proposed Valuation of Other Codes for CY 2016
(5) Mediastinoscopy with Biopsy (CPT Codes 3940A and 3940B)

STS agrees with CMS on its proposal to accept the RUC recommended RVU of 5.44 for code 3940A: Mediastinoscopy; includes biopsy(ies) of mediastinal mass (e.g., lymphoma), when performed. However, STS disagrees with CMS's metholodology and the proposed value of 7.25 RVU for 3940B: Mediastinoscopy, with lymph node biopsy(ies) (e.g., lung cancer staging). STS feels strongly that the RUC-recommended valuation of 7.50 for code 3940B captures the increased time and intensity of work involved and maintains the most accurate relativity between 3940A and 3940B which are the only 2 codes in this family.

The CMS rationale for decreasing the valuation of 3940B from 7.50 to 7.25 inaccurately assumes that the only difference between the 2 codes is 15 minutes of intraservice time. In the proposed valuation of 3940B, CMS fails to consider the other factors besides the time it takes to perform the service. CMS ignored the intensity characterized by added technical skill, physical and mental effort additional judgment and stress involved in the performance of 3940B compared to 3940A. CPT code 3940B requires multiple individually distinct anatomically located lymph node stations be examined not just the biopsy of a single mass as described in 3940A. The intensity of 3940B is further defined by prior non-diagnostic EBUS directed biopsies, which create an inflammatory reaction in these tissue planes, which are intimately involved or adherent to different critical vascular structures. In the proposed valuation, CMS has ignored the robust physician survey and physician expert panel review wherein STS and the RUC concluded that 3940B is a more intense procedure as compared to 3940A.

Further, the CMS argument regarding a discharge day is not relative to the valuation of the services. The codes were re-surveyed as 0 day services and the half discharge day was factored into the valuation of the services.

Finally, within the summary of recommendations (SOR), STS provided additional information supporting the correct valuation of 7.50 for CPT 3940B. STS made comparisons of 3940A and 3940B to the recently RUC-and CMS-valued code "32674 Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)." 32674 is a ZZZ code valued by the RUC in 2011 with RVW 4.12 for 30 minutes of intraservice work and its work is almost identical to the additional work of 3940B. The table below comes directly from the SOR.

CPT Code	CPT Descriptor	Intraservice Time	IWPUT	RVW
3940A	**Mediastinoscopy; includes biopsy(ies) of mediastinal / mass (e.g., lymphoma), when performed**	**45**	**0.071**	**5.44**
32674	**Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy ZZZ**	**30**	**0.137**	**4.12**
1/2 32674		**15**	**0.137**	**2.06**
3940A + 1/2 32674		**60**	**0.088**	**7.50**
3940X2	**Mediastinoscopy; with lymph node biopsy(ies) (e.g., lung cancer staging)**	**60**	**0.088**	**7.50**

The resulting 3940B valuation of 7.50 is exactly the same as the 25th percentile survey magnitude estimation and also a validation of the RBRVS methodology. STS recommends that CMS accept the RUC recommended value of 7.50 arrived at via physician survey data, expert opinion and magnitude estimation for code 3940B.

(19) Low-dose computed tomography, lung, screening (GXXX1) and lung cancer screening counseling and shared decision making visit (GXXX2)

STS agrees with and appreciates CMS's recognition of the importance of lung cancer screening with low dose computed tomography. The counseling visit to discuss the need for lung cancer screening using low dose CT (LDCT) scan for eligibility determination and shared decision making (GXXX2) will be an important aspect of these patients' care. STS agrees with the proposal of 0.52 RVU for this service. As was done for smoking and tobacco-use cessation counseling services, STS encourages CMS to clarify that a medically necessary evaluation and management service on the same day as a shared counseling visit for lung cancer screening with LDCT is allowed when it is clinically appropriate. Similar to smoking and tobacco-use cessation

counseling services, the shared decision-making for the lung cancer screening using LDCT requires additional time and expertise beyond the work included in the E/M encounter with the patient. The same day E/M service should be separately reportable with a -25 modifier to identify a significantly, separately identifiable E/M service on the same day.

III. Other Provisions of the Proposed Regulations

H. Physician Compare Website

STS supports efforts to provide consumers with tools to make them better healthcare decision makers. We also appreciate the steps CMS is taking to ensure that only accurate and meaningful data are made available to the public. However, we continue to have concerns about the rapid timeline for releasing these data, and fear that if they are released prematurely and without adequate testing, it could mislead and confuse the public and even inappropriately harm the reputation of physicians. As such, we urge CMS to work closely with professional societies and clinical experts throughout this process.

To date, we know little about the extent to which CMS has conducted consumer testing and if consumers are even turning to the site for health care decision-making. Furthermore, we urge CMS to release data incrementally in order to give the agency and the public a chance to learn from and improve upon the underlying measures data and reporting formats before further expanding the publicly reported data set. A gradual release of data will also ensure that consumers are not overwhelmed and confused by an abundance of unnecessary information. It is also important that CMS add language to the Physician Compare site explaining why certain professionals might not yet have performance data that is suitable for public reporting and that this is not a reflection of the level of their quality. We highlight a few specific instances below where that distinction is necessary.

3. Proposed Policies for Public Data Disclosure on Physician Compare

a. Value Modifier

STS remains concerned about the relevance of the quality and cost measures used to calculate the value modifier (VM), the ongoing disconnect between what is being measured on the quality side and cost side of the equation, and the inadequacy of the program's attribution and risk adjustment methodologies. For example, CMS relies on PQRS measures to calculate a portion of the quality composite, which focuses on very specific procedures or services (e.g., discontinuation of prophylactic antibiotics) while the cost measures are broad and evaluate total costs (i.e., total per capita costs, as well as the cost of services performed during an episode that comprises the period immediately prior to, during, and following a patient's hospital stay). As a result of these concerns, we oppose any effort to provide the public with information about VM adjustments or tiers, regardless of whether this information is posted on physician profile pages or a downloadable database.

Instead, we recommend that CMS continue to provide VM data confidentially to physicians so that they can help CMS to refine these measures and methodologies going forward. We also recommend that CMS work with professional societies to identify examples of where the cost

and quality measure disconnect is most problematic and to how to resolve those disconnects so that patients can make a better informed value judgment about physicians.

As part of an expansion of public reporting on Physician Compare, CMS proposes to add a green check mark to the profile page of the Physician Compare Web site for providers receiving an upward adjustment under the VM starting in CY 2018. STS is concerned that entities that have not previously reported will receive a lower mark than the quality of their performance would have otherwise afforded them if there were sufficient data available. We encourage CMS to include a disclaimer on the VM portion of the Physician Compare information that states a lack of information does not constitute poor performance.

b. Million Hearts

CMS proposes to add an indicator for individual eligible providers (EPs) who satisfactorily report the new proposed Cardiovascular Prevention measures group on Physician Compare. STS urges CMS to clearly state on the Physician Compare website that EPs who do not receive an indicator for the cardiovascular prevention measures group may still satisfactorily meet individual measures within the group, even if they do not receive a check mark for having reported on all the relevant measures. We are concerned that this type of public reporting will give patients the mistaken impression that physicians are poor performers rather than accurately depicting them as not reporting on all the measures.

e. Individual EP and Group Practice QCDR Measure Reporting

STS supports the rationale behind the CMS decision to wait before making individual EP level QCDR PQRS and non-PQRS measure data available for public reporting yet we are concerned that QCDRs might not be ready for public reporting beyond a measure's first year. Since QCDRs have the flexibility to determine the manner in which they publicly report their own data, it is important that they are given the opportunity to conduct careful analyses regarding the validity, reliability, and accuracy of measures data, as well as utility to consumers. QCDRs may need more than one year to conduct these analyses and to develop evidence-informed benchmarks that make measures data suitable for public consumption. QCDRs also need time to gain experience collecting and reporting data to CMS and resolving any inaccuracies in the data before releasing data to the public. This issue recently came to light when CMS announced that it had identified multiple errors and inaccuracies related to the Performance Year (PY) 2014 submission data. As a result, CMS cannot use these data to determine quality performance and/or establish benchmarks for the 2014 reporting year.

f. Benchmarking

CMS proposes to publicly report on the PQRS performance rates most recently available against an item- or measure-level benchmark that is derived using the Achievable Benchmark of Care (ABC) methodology. The proposed rule also states, "Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure's performance rate during the year prior to the performance period." While

we appreciate CMS's efforts to put performance data into context so that they are more useful to consumers and physicians, we have multiple concerns and questions about the ABC methodology's ability to accomplish this goal. We seek more clarity regarding the ABC methodology's benchmark, which is based on the mean of the best performers on a given measure representing at least 10 percent of the patient population. Specifically, how was validity and reliability determined for the best performers across all PQRS measures? STS is also unsure to what extent the ABC methodology would adequately account for patient mix and ensure apples-to-apples comparisons of physician performance.

In addition, STS maintains that the most reliable national benchmarks of physician quality performance are generated from established clinical registries like the STS National Database. It is very important that CMS preserve the freedom it has afforded to QCDRs up until this point to determine the best mechanism for benchmarking and publicly reporting its own measure data. Creating new benchmarks may cause confusion among consumers. STS requests clarification as to whether a QCDR will be able to submit its own data or if CMS will take data submitted by the QCDR to calculate the mean. It is important to note that if CMS plans to take the submitted data from the QCDR and calculate the mean, QCDRs should be able to risk adjust those data first.

Moreover, to ensure that methodologies are easily understood by physicians and the public, CMS should aim to use consistent and transparent methodologies across programs to the greatest extent possible. This alignment is especially important for Physician Compare and the Value Modifier/ Quality and Resource Use Reports (QRURs), which rely on the same PQRS quality measures.

h. Downloadable Database

CMS is proposing to add the 2018 VM quality tiers for cost and quality (based on the 2016 data) to the Physician Compare downloadable database for group practices and individual EPs. The data will indicate if the group practice or EP is high, low, or average performer on cost and quality metrics per the VM program. STS encourages CMS to put in place a 30-day period for EPs and group practices to review any information that will be added to the VM in the downloadable database. As noted in the proposed rule, the database is geared toward health care professionals, industry insiders, and researchers who are more able to accurately use more complex data. As CMS enhances transparency and entities utilize the complex data for reports on physician performance, it is essential that EPs have time to verify the accuracy of the information as well as have access to an appeals process should the information be incorrect. STS also believes that consumers and other entities accessing the downloadable database would benefit from the added explanation that costs are impacted by type of institution and geographic location.

Measure Stratification - CMS proposes to include on Physician Compare individual EP and group practice-level quality measure data that is stratified by race, ethnicity and gender. STS does not collect data on all of the areas mentioned above, nor can it be mandatory for EPs to report personal health information given the privacy limitations under the Health Insurance Portability and Accountability Act. As CMS determines how best to stratify quality measure

data, we request that it keep in mind the unique limitations of each PQRS reporting mechanism, which might make it difficult to collect this information. For example, claims data might not adequately capture the breadth of socio-demographic factors that CMS would like to account for. And while a clinical data registry might have more flexibility to customize its data points, doing so could create an additional data collection burden on participants if the registry cannot easily extract this additional information from an EHR or other source due to lack of interoperability or uniformity of data definitions. Should CMS move forward with listing measure data that is stratified by race, ethnicity and gender on Physician Compare, STS encourages a phased-in approach as well as a disclaimer that such information is provided on a voluntary basis.

I. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

2. Requirements for the PQRS Reporting Mechanisms

a. Self-Nomination Requirements

STS appreciates the attempt by CMS to give QCDRs more time for self-nomination by opening the period a month earlier (i.e., December 1 through January 31). We also appreciate the proposal to require that an entity be in existence as of January 1 of the year for which the entity seeks to become a QCDR rather than the year prior. This provides more flexibility and provides a wider variety of registries in various stages of implementation the opportunity to become a QCDR.

Nevertheless, we are concerned about the proposal to move up the date by which an entity must submit all documents to CMS for purposes of being considered a qualified QCDR. Under current policy, vendors have until March 31 to provide CMS with such information. Documentation includes, but is not limited to, submission of the vendor's data validation plan as well as the measure specifications for the non-PQRS measures the entity intends to report. Under this latest proposal, after the entity submits this information on January 31, it cannot later change any of the information it submitted for purposes of qualification. However, CMS could still request supplemental information from the entity after this date. Getting this documentation in order by January 31 could be a challenge, especially for entities that are applying to become a QCDR for the first time or entities that have decided to submit new measures. Many QCDRs used the first three months of 2015 to ask CMS important questions about the QCDR requirements and the adequacy of their measures and methodologies before submitting their final nomination. We request that CMS preserve this important opportunity by maintaining the March 31 deadline.

b. Proposed Changes to the Requirements for Qualified Registries

For the 2018 PQRS payment adjustment, CMS proposes new requirements as part of the data validation strategy for verifying the QCDR data. These requirements include an indication of "the method the entity will use to verify the accuracy of each [TIN] and [NPI] it is intending to submit (that is, National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation)." CMS appears to expect QCDRs to collect NPI and tax documentation from EPs to satisfy this requirement. Previously, CMS had only requested that QCDRs submit a

validation strategy to CMS outlining how it intends to verify that each EP has successfully met individual measures and that their data is true, accurate and complete.

We believe that provider verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements. Presently, QCDRs may have different strategies to meet the data validation requirements. Requiring all QCDRs to collect NPI and tax documentation from each EP as part of a data validation strategy is unduly burdensome. Provider verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements.

6. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2016 and Beyond for Individual EPs and Group Practices

d. PQRS Quality Measures Groups

CMS proposes to add the cardiovascular prevention measures group to PQRS. While STS understands the impetus behind proposing a measures group for cardiovascular prevention, we are concerned that: (1) QCDRs do not report measures groups; and (2) our members would only satisfactorily meet three of the measures in the proposed group (e.g., Preventive Care and Screening: Tobacco use; Statin Therapy for the Prevention and Treatment of Cardiovascular Disease; and Ischemic Vascular disease: Use of Aspirin or Another Antithrombotic).

STS encourages CMS to permit credit for the cardiovascular measures reporting at both an individual and group level. Since QCDRs are unable to report measures groups, they will need to report individual applicable measures for EPs for both the proposed cardiovascular prevention measures group and the proposed Coronary Artery Bypass Graft (CABG) measures group. If CMS permitted this change, EPs whose practices do not inherently allow them to perform all of the measures in the cardiovascular measures group would have the opportunity to receive credit for successfully reporting on the individual measures within the group, and QCDRs can successfully report on the CABG measures group on behalf of individual EPs.

7. Request for Input on the Provisions Included in the Medicare Access and CHIP Reauthorization Act of 2015

a. The Merit-based Incentive Payment System (MIPS)

Clinical Practice Improvement Activities

STS supports many of the examples of clinical practice improvement activities that were included in the Medicare Access and Chip Reauthorization Act (MACRA) statute. In particular, we are grateful that participation in a QCDR, use of surgical checklists, and practice assessments related to maintenance of certification were included as clinical practice improvement activities. We would suggest that tools like the STS Risk Calculator (http://www.sts.org/quality-research-patient-safety/quality/risk-calculator-and-models/risk-calculator) be included among the shared decision-making mechanisms mentioned in the statute. The STS Risk Calculator allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal

failure. The Risk Calculator incorporates STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

While we support the inclusion of clinical practice improvement activities in the MIPS performance score, we also endorse the relative weight of this component as compared to the other MIPS provisions. We would note that the statute provides little guidance on how to implement the clinical practice improvement activities requirement and caution CMS not to unintentionally overburden physicians with these check-the-box requirements as they work to achieve high scores on the other, more heavily-weighted components. Credit should be given for adoption of new clinical practice improvement activities and maintenance of existing activities that have been shown to add value and quality. Physicians should not be required to complete one activity in every category but select those categories that best fit their practices. While the activities themselves should yield positive changes that will benefit patients, making this aspect of the MIPS program too rigid could have dire consequences for physicians who are trying to acclimate to a new payment structure.

b. Alternative Payment Models

STS maintains a long standing practice of supporting innovative ideas to improve health care quality and reduce overall health care costs. In anticipation of APM policy becoming a reality, STS convened a meeting of our society's thought leaders and policy and registry experts in late 2013. That group examined the procedures most frequently performed by STS members and began to formulate alternative payment models for the Heart Team and Lung Cancer Care Team. For example, for the Heart Team Model, we considered an incremental approach to implementation that we believe will result in a longitudinal disease management bundled payment for Heart Team care. We are confident that we can use the STS National Database, combined with other sources of administrative claims and quality information, to promote patient-centered, team-based care that rewards all members of the patient's care team for putting the patient first. This approach can improve patient outcomes and patient satisfaction while also improving care efficiency and saving money by enabling the care team to identify and provide the right treatment at the right time.

While our APM models are not yet finalized, we would like to demonstrate that STS is ready and eager for this opportunity. We look forward to providing a more specific response to the forthcoming RFI and working with CMS to see the Heart Team and Lung Cancer Care Team APM come to fruition.

N. Physician Self-Referral Updates

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

CMS requests comments on any additional guidance or rulemaking relating to the physician self-referral law that may be required to facilitate the design and implementation of APMs. STS appreciates the forethought demonstrated by CMS in this request. However, because we have not yet finalized our APM proposals, it is difficult to say what aspects of this law may unnecessarily

hinder provider collaboration and gainsharing in this context.

Because the APM implementation process has a robust development and evaluation phase, we would recommend that CMS use that period to ascertain the types of financial relationships that should be subject to exception and what conditions should be placed on those exceptions to protect patients. CMS experts and the technical advisors serving on the Physician-Focused Payment Model Technical Advisory Committee will be in a position to collect real information on how the self-referral laws are working to support or hinder APM development. Evaluators should be given the authority to approve the programs that they believe will work and make recommendations to CMS for any changes to self-referral laws that should be adopted including those related to shared savings or gainsharing arrangements.

Other

We hope to work with CMS to ensure that the claims data that are shared with QCDRs under the new MACRA authority contain verification of Medicare beneficiary life status and date of death (if applicable) as authorized by 42 USC §405(r)(9).

Section 105(b) of MACRA requires CMS to make Medicare claims data available to QCDRs so that patient outcomes information can be linked with the robust clinical information contained in registries. We are extremely eager for implementation of this important policy and look forward to working with the administration to ensure that clinical data are transmitted to registries in a timely yet secure manner. As CMS is aware, clinical data from registries yield sophisticated clinical information and allow for risk-adjustment while administrative data will provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs. The patient outcomes information derived from the combination of these data sources will not only have a variety of quality improvement and research implications, they will also help physicians educate today's patients and families so that they can play an active and informed role in the shared decision-making process.

Tracking patient outcomes is a critical part of the Society's ongoing quality implement and effectiveness research efforts. Linking clinical registries to the Social Security Death Master File (SSDMF) once allowed for the verification of "life status" of patients who otherwise would be lost for follow up after their treatment. Unfortunately, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the SSDMF so as to protect those listed in the file from identity theft. Balanced against legitimate privacy concerns are the many advantages of linked administrative and outcomes data when placed in the right hands, with adequate protections in place. Fortunately, the Secretary of Health and Human Services has the authority under 42 USC §405(r)(9) to match Medicare claims data with death data contained in the full SSDMF data file (not just the public DMF available to entities that meet certification criteria). Because our ultimate purpose for accessing death data was patient outcomes information, including verification of patient life status and date of death and not the acquisition of the actual death data set itself, we urge the Secretary to exercise this authority prior to sharing Medicare claims data with QCDRs.

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

Sincerely,

Mark S. Allen, MD
President