STS Headquarters
633 N Saint Clair St, Suite 2100
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org

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

September 23, 2020

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

Re: CMS-1734-P; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Verma,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Fiscal Year (FY) 2021 Physician Fee Schedule (PFS) Proposed Rule. 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.

The below comments address the following sections of the PFS Proposed Rule:

Contents

General Comments

We are deeply concerned that the proposed sharp cuts to reimbursement will amplify the financial instability practices are already experiencing due to the COVID-19 pandemic. The pandemic caused delays in care and sharply reduced patient care volumes that in many cases led to difficult but unavoidable financial decisions, including reduced staffing. Delayed care has also exacerbated many patient conditions that will now require even more specialized treatment. As patient care slowly becomes more possible during and after the pandemic, many practices and health care systems that depend on procedures to regain financial stability and reestablish pre-pandemic staffing levels will instead be hit by another financial crisis in January: substantial cuts to Medicare payments for professional services. CMS proposes in this rule to drastically reduce payment across the majority of specialties primarily due to the roll-out of Evaluation and Management (E/M) codes representing more complex care and greater physician work even as these specialties have actively contributed to both patient COVID-19 treatment and health system financial recovery.

Although cardiothoracic surgery is one among many specialties negatively impacted by these cuts, we are specifically concerned with the impact 9% and 8% cuts will have to patient access to cardiac and thoracic surgery, respectively. Especially in the Medicare population, cardiac and thoracic surgery is often critical to beneficiaries' health outcomes. At 25% of all cancer deaths, lung cancer is the leading cause of cancer death in the U.S. and worldwide—it is estimated over 135,000 lung cancer deaths will occur in 2020 in the United States.[1] The Medicare population shoulders the majority of this disease burden—the average age of people diagnosed is 70.[2] Heart disease is the leading cause of death in the United States and accounts for 1 in every 4 deaths.[3]

Cardiothoracic surgeons have also played a key role in treating COVID-19 patients who have not responded to standard treatments. When other treatments, including ventilator support, fail to improve a patient's respiratory function, cardiothoracic surgeons may use extracorporeal membrane oxygenation (ECMO), a treatment which re-oxygenates the blood, and in select cases lung transplantation.

Cardiothoracic surgery practices facing financial hardship due to the combined effect of the pandemic and the Medicare cuts will unfortunately face tough choices to remain financially viable. These choices

[1] https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html
[2] https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html
[3] https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20leading,1%20in%20every%204%20deaths

will likely impact patient access to care, staffing levels, investment in new treatment technology, surgeon training, and clinical research of new treatments. These impacts will unfortunately be felt most acutely among underserved populations and geographic areas that already face financial hardship and care shortages.

Even without consideration of the COVID-19 pandemic, the proposed cuts are devastating to cardiac and thoracic surgery. We have outlined in this comment letter our concerns and suggestions to prevent harm to surgical practices and patient access to cardiac and thoracic surgery. STS urges CMS to avoid these unintended negative impacts to Medicare patients and instead work with the national medical specialty societies and providers to find solutions that bring the most benefit to patients.

VIII Regulatory Impact Analysis *(taken out of order)*
C. Changes in Relative Value Unit (RVU) Impacts

CMS estimates the CY 2021 PFS CF to be $32.2605, a 10.6% decrease which reflects the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act and the statutorily-mandated budget neutrality adjustment. In the Regulatory Impact Analysis, CMS indicates that the provisions in the evaluation and management (E/M) section of the rule are the largest contributor to the CMS calculation of the budget neutrality adjustment to the conversion factor. This includes the widespread specialty impacts related to the proposed changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes.

CMS proposes to make changes in the work RVUs for services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes, as many services have E/M visits "explicitly built into their definition or valuation." Services that CMS is proposing to revalue since they are analogous to the office and outpatient E/Ms include the following: End-Stage Renal Disease (ESRD) Monthly Capitation Payment Services, Transitional Care Management (TCM) Services (99495, 99496), Maternity Care Services, Assessment and Care Planning for Patients with Cognitive Impairment, Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness Visits (AWV), Emergency Department Visits, Therapy Evaluations and Behavioral Healthcare Services.

At the same time, CMS is not proposing increases to the ophthalmological services that were requested for review based on the premise that they have not been reviewed by the RUC since 2007 and they are "not sufficiently analogous or connected to the office/outpatient E/M visits" even though they have historically been valued related to those services. CMS is also not recommending that the office/outpatient E/M visit increases be passed through to the 10- and 90-day global services as they have been in the past and recommended by the AMA/Specialty Society RVS Update Committee (RUC). CMS states that they did not "make changes to the valuation of the 10- and 90-day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while they continue to collect and analyze data on the number and level of office/outpatient E/M visits that are actually being performed as a part of these services."

Evaluation and Management Codes

The series of changes proposed by CMS in this proposed rule indicate that the agency is continuing its mission to re-engineer the healthcare system through a series of reimbursement decisions, by taking what was designed to be an objective RUC process for valuing codes and altering the outcomes to achieve their own self-defined goals without legislative authority or oversight. CMS has within its power, the ability to mitigate potential damage to the health care system in the midst of a public health and economic crisis while still achieving its objective to increase payments for office/outpatient E/M services.

The cuts related to the budget neutrality requirement, paired with the failure to incorporate the revised office/outpatient E/M values in the global codes, will result in drastic cuts to many physician specialties. These cuts come at a time when specialists are struggling with the financial impact of the COVID-19 pandemic in many ways, including pay cuts from the suspension of elective surgery, salary reductions, furloughs, and layoffs. We urge CMS/HHS to utilize its authority under the public health emergency declaration to implement the office visit increases as planned waiving budget neutrality requirements for the new Medicare office visit payment policy, which would help significantly to preserve patient access to care and mitigate financial distress due to the pandemic.

Extracorporeal membrane oxygenation (ECMO) is the treatment of last resort when COVID-19 patients fail to recover with ventilator support. A cardiothoracic surgeon is typically involved in treating patients with ECMO, which is a lifesaving technique where a machine replaces the function of the lungs and/or heart, giving the patient's body a chance to rest and recover under the supervision of cardiothoracic surgeons and other health professionals trained in this specialized treatment. Cardiothoracic surgeons have contributed to the care of critically ill COVID-19 patients during the pandemic. Cardiothoracic surgeons treat patients affected by three of four leading causes of death in the United States: heart disease, cancer (lung and bronchus), chronic lower respiratory disease. Medicare reimbursement cuts could hinder patient access to life-saving care for these diseases.

CMS claims that their proposal to revalue services analogous to office/outpatient E/Ms does not have a significant impact on the drastic 11% reduction in the Medicare conversion factor as necessitated by proposed additional spending of $10.2 billion. CMS' proposal to reduce the Medicare conversion factor from $36.0896 to $32.2605, a - 10.6 percent decrease, lowers the 2021 conversion factor below the 1994 conversion factor of $32.9050, which would be approximately $58.02 today in current dollars. This extraordinary cut to the conversion factor is triggered by a number of proposed increases to the values of many bundled services that are comparable to or include office/outpatient E/M visits. The additional spending to support these increases, along with the increases to stand-alone office/outpatient E/M visits, totals $10.2 billion. Only half of the additional spending, and therefore, half of the reduction comes from the RUC-recommended changes. The remaining spending increases and resulting conversion factor reduction is attributed to various CMS proposals to increase valuation for specific services and the GPC1X "complexity" add-on code. The GPC1X is CMS' sole creation and was not nationally surveyed by the RUC. GPC1X alone accounts for $3.3 billion and the remainder from services CMS has deemed as analogous to office and outpatient E/Ms.

STS strongly disagrees with CMS' proposal to revalue services analogous to office and outpatient E/M visits without formal review of those codes. It is inconsistent of CMS to consider increasing values that

are closely tied to the values of the office/outpatient E/M visit codes and/or codes that have E/M visits "explicitly built into their definition or valuation" for some services and not others. CMS' proposal to increase the values for the End-Stage Renal Disease (ESRD) Monthly Capitation Payment Services, Transitional Care Management (TCM) Services, Maternity Care Services, Assessment and Care Planning for Patients with Cognitive Impairment, Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness Visits (AWV), Emergency Department Visits, Therapy Evaluations and Behavioral Healthcare Services but not the Ophthalmological Services or the E/M visits included in the global surgical package is incongruous. It is especially concerning since there are office/outpatient E/M visits that are actually included in the global surgical package, so the relationship to the changes is absolute. As with other potentially misvalued services (over or under paid), the codes identified by CMS that do not have the office/outpatient E/M codes built in as an independent variable of the code should be subject to the same process for other potentially misvalued services. The services that CMS has identified as analogous to the office/outpatient E/M visit codes should be submitted as potentially misvalued services and subject to review by the RUC and surveys to determine if in fact an increase is warranted. Many of the identified codes haven't been reviewed for several years and there is no evidence that the work has increased comparable to the E/M office/outpatient visit codes. CMS should obtain data to support any changes in the work or practice expense related to any service, including those that are considered analogous to the office/outpatient E/M codes.

Conversely, the global surgical service values have been provided to CMS with the recommendation of the AMA RUC. The global surgical codes are designed to include both in-hospital and outpatient E/M visits. The revised E/M codes are specific to office/outpatient visits, yet CMS has universally declined to apply recommended work and time incremental increases for this aspect of care provided in the post-operative period, which is inconsistent with their past actions. We reiterate that it is inappropriate for CMS to not apply the RUC-recommended changes to global codes starting in CY 2021. To do otherwise will:

- Disrupt the relativity in the fee schedule: CMS is effectively and arbitrarily changing the values for some E/M office visit services, but not others, disrupting the relativity between codes across the Medicare physician fee schedule. This relativity was mandated by Congress, established in 1992, and has been refined over the past 27 years. Historically, CMS itself has ensured this relativity between office/outpatient E/Ms by increasing the value to global services because of the direct relationship between the codes in the significant revaluations of office/outpatient E/Ms in 1997, 2003, and 2011.
- Create specialty differentials: Per the Medicare statute, the "Secretary may not vary the…number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."[4] Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, in violation of the law.
- Ignore recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the post-operative visits of the global surgery codes for each CPT code with a global of 10- day, 90-day and MMM (maternity).

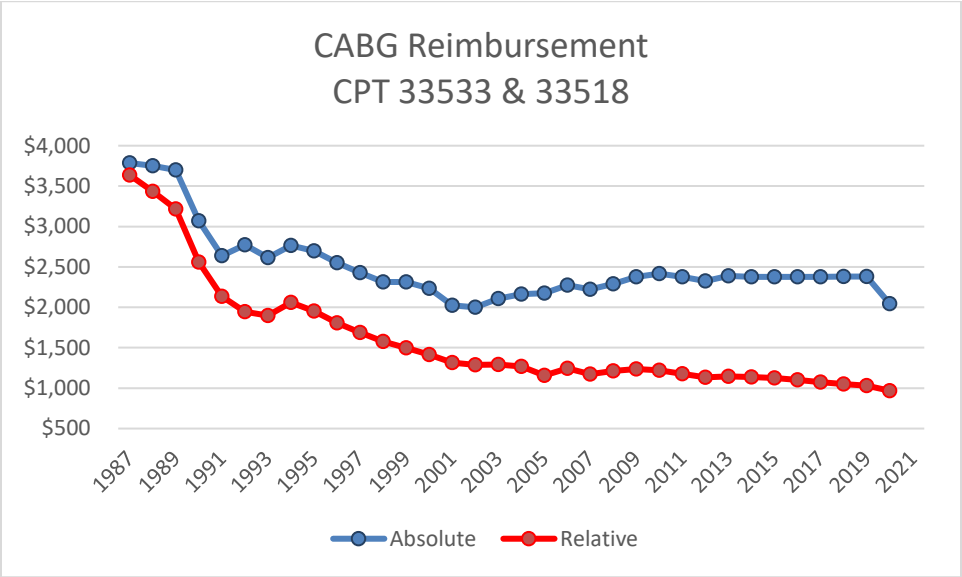
[4] 42 U.S. Code §1395w-4(c)(6)

The RUC also recommends that the practice expense inputs should be modified for the office visits within the global periods.

- Inappropriately rely on section 523(a) of MACRA: In the CY 2021 PFS proposed rule, CMS refers to its decision in the CY 2020 PFS final rule to not make changes to the valuation of the 10-and 90-day global surgical packages to reflect the increased values for the office/outpatient E/M visit codes while the agency continues to collect data on the number and level of post-operative visits included in global codes as required by MACRA. The MACRA data collection requirement, set forth in section 523(a), does not prohibit CMS from applying the RUC-recommended incremental increases to the office/outpatient E/Ms codes to global codes. In fact, section 523(a) specifically authorizes CMS to adjust surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project. In addition, it is inappropriate for CMS to rely on the implementation of MACRA, which passed in 2015, as a reason to refrain from making necessary updates in 2021. This inaction unfairly punishes a subset of physicians who additionally, like all healthcare practitioners, are experiencing the pressures of a global pandemic.

CMS' failure to incorporate RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes in the global codes is unacceptable, particularly in light of the adjustments proposed for other bundled services, such as the maternity codes. Increasing the visits bundled into the surgical global payment would increase spending by approximately $440 million, requiring an approximate 0.4% reduction to the Medicare conversion factor. This is a minor budget neutrality impact in comparison to the impacts proposed for the increases to the stand-alone office visits and other CMS proposals. Organized medicine has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values in the global codes, as evidenced by the many comment letters and meetings over the past year. We are, therefore, deeply disappointed that CMS continues to ignore these recommendations in the CY 2021 Medicare PFS proposed rule.

As an example of the drastic cuts to reimbursement for cardiothoracic surgery over time, since 1987, reimbursement for a three vessel (one artery, two veins) coronary artery bypass graft (CABG) has dropped precipitously to less than one quarter of its original value (in relative terms). It is difficult to see how further changes to reimbursement would not negatively impact patients' access to care, especially as hospitals and health systems are struggling to account for huge economic losses.



GPC1X Add-on Code

The impact of the GPC1X, the E/M add-on code, proposed by CMS should be withdrawn and re-examined given its significant impact to the overall fee schedule and continued confusion about the underlying intent, definition and potential use of the code. CMS assumes that add-on code GPC1X will be applied to 75% of all office visit claims, costing the Medicare program $3.3 billion annually. This add-on code alone will account for a 3.5% reduction in the conversion factor. CMS has not provided a clear definition for GPC1X and, in fact, the code descriptor for GPC1X is different throughout different sections of the notice of proposed rulemaking (NPRM). Additionally, no information on the typical patient for the code and how that patient differs from the typical patients for the revised E/M codes has been provided. CMS' assertion that ongoing care related to a patient's single, serious, or complex chronic condition is not captured with the level 5 office/outpatient E/M visit, which describes seriously ill, complex patients, is not substantiated with any information on what additional resources are involved in the add-on code that are above and beyond the revised office/outpatient E/M codes, the new prolonged service code, other CPT codes or the telehealth codes. Additionally, it is not clear how the time associated with GPC1X differs from the time-based services defined by the new prolonged services code. If CMS still believes cognitive specialty codes to be misvalued, even after the most recent RUC response to the original CMS E/M proposal, then it should work with CPT, RUC, and the national medical specialty societies to develop appropriate codes and value them within the existing process. However, it is worth noting that the CPT/RUC Workgroup on E/M did not include a code analogous to GPC1X in its E/M revisions and the RUC itself was nearly unanimous in its support of the revalued E/M proposal, absent the add-on code.

In order to ensure practices facing severe economic strain and uncertainty are able to continue meeting the needs of patients during and after the pandemic, STS strongly urges CMS/HHS to use its authorities and flexibilities under the Public Health Emergency (PHE) to implement the office visit increases and waive the requirement for CMS to adjust Medicare physician payments for budget neutrality when it

implements the office visit coding and payment changes that it has finalized for 2021. We also urge CMS to apply the RUC recommended changes to the office/outpatient E/M component of the global codes to maintain the relativity of the fee schedule.

II. Provisions of the Proposed Rule for the PFS

B. Determination of PE RVUs

CMS indicates that they had the RAND Corporation study potential improvements to CMS's practice expense (PE) allocation methodology and the underlying data. Based on the TEP and RAND's ongoing research, CMS is interested in potentially refining the PE methodology and updating the data used to make payments under the PFS. CMS is soliciting comments on how it might update the clinical labor data, which has historically been derived from Bureau of Labor Statistics, and whether this is the best data source or if there is an alternative. CMS also requests feedback on the RAND report. In addition, CMS indicates that they plan to host a Town Hall meeting to discuss their ongoing research to potentially update the PE methodology and the underlying inputs with stakeholders.

CMS currently uses data from the U.S. Bureau of Labor Statistics (BLS) to determine a cost per minute estimate for each of 50 different clinical staff professions. STS supports continued use of the BLS to determine clinical labor costs. The BLS is a reliable and transparent source of data. STS encourages CMS to continue using BLS to determine clinical labor costs using the most recent year of available BLS data to ensure that clinical labor costs are up-to-date.

STS supports CMS' proposal to convene a Town Hall meeting to discuss their ongoing research and potential update of the PE methodology and the underlying inputs with stakeholders. We feel that it is important for CMS to work with the AMA, RUC, and national medical specialty societies regarding any potential changes to the underlying PE methodology to ensure an effective, transparent, and fair data collection effort. The AMA notified the national medical specialty societies about their 2020 AMA Practice Expense Pilot Study and their intent to conduct a large scale Practice Expense Survey. In 2007-2008, the AMA conducted the *Physician Practice Information (PPI). The PPI survey* was conducted to update the specialty-specific practice expense per hour data used to develop practice expense relative value units and collected current, reliable practice expense data using a consistent survey instrument for all specialties and health care professionals at that time. The Administration indicated that the PPI survey was the most comprehensive source of practice expense survey information available at that time and began using the data obtained from the PPI survey in determining 2010 Medicare payments. STS urges CMS to begin working with the AMA to conduct a comprehensive practice expense survey in 2021 to collect updated data that can be used in determining Medicare payments.

2021 Anticipated Specialty Assignment for Low Volume Services Code List

The Society appreciates that CMS has included all of the low-volume cardiothoracic surgery codes in the 2021 anticipated specialty assignment for low volume services and that malpractice (MP) adjustments are reflected in the proposed MP relative value units (RVUs). The remaining concern the Society has with the 2021 list is issue of the incorrect specialty assignment to a number of the codes. We have repeatedly over the last several years commented on a number of low-volume services where CMS has assigned the wrong specialty to services included on the list. CMS persists to ignore STS corrections highlighting their continued general confusion about the distinction between cardiac surgery and

thoracic surgery. The 2021 *Anticipated Specialty Assignment for Low Volume Services* Code List includes a number of services that had been assigned to Cardiac Surgery after our comments in 2019. For CY 2020, CMS reassigned them to Thoracic Surgery. The Society and the RUC have provided information on the expected specialty for these codes when the expected specialty list was developed and have been consistent in our comments over the past several years as to the correct specialty assignments for these codes. We once again ask that CMS correct its mislisting and permanently assign the codes listed in Appendix A of this letter to the indicated specialty. The Society is still concerned that services identified in Appendix A that are erroneously assigned as thoracic surgery procedures instead of cardiac surgery procedures or that have not been assigned to the correct specialty, could adversely impact the MP RVUs.

Additionally, while the malpractice risk factor for both cardiac surgery (6.37) and general thoracic surgery (6.45) is naturally very similar, we are still unclear as to why the thoracic malpractice risk factor is slightly higher than the cardiac surgery malpractice risk factor.

D. Telehealth and Other Services Involving Communications Technology
b. Requests to Add Services to the Medicare Telehealth Services List for CY 2021

CMS is proposing to add services to the Medicare Telehealth Services List for CY 2021. In response to the COVID-19 Public Health Emergency (PHE), CMS implemented emergency rulemaking to add Medicare telehealth services on an interim final basis in the April 6th "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" interim final rule with comment period ("4/6 IFC"). CMS reviewed which of these services should remain on the Medicare telehealth services list permanently or on an interim basis, as well as other requests to add services and requests CMS identified.

CMS is proposing to add the following services to the Medicare telehealth services list on a Category 1 basis for CY 2021:

- *Group psychotherapy (CPT code 90853)*
- *Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99334-99335)*
- *Home Visits, Established Patient (CPT codes 99347- 99348)*
- *Cognitive Assessment and Care Planning Services (CPT code 99483)*
- *Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS code GPC1X)*
- *Prolonged Services (CPT code 99417)*
- *Psychological and Neuropsychological Testing (CPT code 96121)*

STS strongly disagrees with creation of the GPC1X add-on code for reasons explained above. As such, STS does not support the addition of the GPC1X code to the telehealth services list. Adding GPC1X to the telehealth services lists is inappropriate. There is still a significant amount of confusion surrounding the add-on code and concerns with its significant impact on the fee schedule. The definition of the code and the work involved is still not clear. CMS' assertion that the newly revised E/M office/outpatient visit codes and other CPT codes do not cover the work of longitudinal complex evaluation and management services and assumption that it only applies to select specialties is unfounded. Additionally, their assertion is in conflict with the CPT/RUC Workgroup on E/M.

STS supports the addition of the new prolonged office or other outpatient evaluation and management services(s) add-on code 99417 to the Medicare telehealth services list. This code allows physicians a method to report the additional work required for virtual evaluation and management patient visits that require additional time and with appropriate compensation.

c. Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List

CMS is proposing to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. This new category would describe services included on the Medicare telehealth services list on a temporary basis. CMS includes in this category services that were added during the COVID-19 PHE that likely exhibit a clinical benefit beyond the PHE but are not yet sufficient to meet the category 1 or category 2 criteria.

CMS invites public comment suggesting pertinent information to consider as part of the clinical assessment.

STS applauds CMS for establishing a pathway for telehealth services that have demonstrated clear clinical benefit to remain covered even after the COVID-19 PHE concludes. The Society suggests considering the following evidence as part of category 3 clinical assessment of services:

- Decrease in ED admissions
- Decrease in readmissions
- Improved access for underserved populations and patients, including rural locales
- Increase in patient satisfaction

As CMS recognizes, formal analyses of these services may not be available yet. However, STS is confident that data collected during COVID-19 will demonstrate the positive impact telehealth has had on both patient clinical outcomes and patient experiences. There is some data to support that telehealth services play an important role in decreasing readmissions and emergency department treatments and providing rural patients with access to otherwise limited resources. Some VA studies have shown high patient satisfaction with telehealth services and no increase in mortality. Advances in technology and the advent of more sophisticated equipment has increased the extent of patient monitoring via telemedicine and has resulted in increased physician and patient satisfaction. Anecdotally, many patients have reported to STS members that these services have enabled them to feel more connected to their provider and engaged in the health care experience. Although this is likely true for all patients, we recommend CMS continue to broaden the scope of telehealth services coverage and reimbursement and particularly consider impacts to traditionally underserved patient populations and geographic locations.

d. Comment Solicitation on Medicare Telehealth Services Added on an Interim Basis during the PHE for the COVID-19 Pandemic that CME is Not Proposing to Retain After the PHE Ends
5. Communication Technology-Based Services (CTBS)

CMS is proposing to establish new codes G20X0 and G20X2 that would enable practitioners who cannot independently bill for E/M services to bill for certain remote evaluation and brief communication services via telehealth. Currently, only practitioners that can furnish E/M services are able to bill the existing and

analogous HCPCS codes G2010 (Remote evaluation of recorded video and/or images) and G2012 (Brief communication technology-based service, e.g. virtual check-in). Although CMS proposed valuing the new G20X0 and G20X2 codes equal to the existing G2010 and G2012 codes, CMS solicited comment inquiring whether the existing HCPCS codes should be revalued and potentially increased.
Given that CMS acknowledged it typically applies a higher value to services performed by practitioners who can independently bill E/M services, STS supports revaluing to increase the existing G2010 and G2012 codes to ensure consistency and accurately reflect the type of practitioner providing services.

STS supports the creation of new telecommunication codes that allow certain nonphysician practitioners who cannot independently bill for E/M services to report their services consistent with the definition of their respective benefit category. However, STS does not agree that the services should be valued the same as those provided by physicians and encourages CMS to increase the valuation of *G2010 and G2012.*

6. Continuation of Payment for Audio-only Visits

In the 4/6 Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency interim final rule with comment (IFC), HHS/CMS established separate payment for audio-only telephone evaluation and management (E/M) services (99441-99443) on a temporary basis for the duration of the COVID-19 PHE. Additionally, in the May 8th IFC (5/8 IFC), CMS increased payment and placed these services on the Medicare telehealth services list. CMS is proposing not to continue to recognize these codes for payment after the conclusion of the PHE.

STS supports some provision of payment for audio-only visits in appropriate circumstances. Although the Society does not believe that audio-only is adequate for more complex visits, we acknowledge that use of audio-only visits during the COVID-19 PHE has demonstrated a legitimate benefit. Therefore, STS supports CMS in seeking to develop coding and payment for some audio-only visits.

However, STS cautions that after the COVID-19 PHE, visits suitable for audio-only are likely less complex than in-person visits and video visits and therefore it would not be appropriate to be compensated at the same rate. As such, STS recommends that any audio-only services be sent through the valuation process to ensure that they are appropriately valued.

9. Direct Supervision by Interactive Telecommunications Technology

For the COVID-19 PHE, CMS has adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology. CMS is proposing to extend this policy to either the end of the calendar year in which the COVID-19 PHE ends or December 31, 2021. Virtual presence includes audio/video real-time communications technology (excluding audio-only).

STS supports permanently extending the option for virtual supervision when clinically appropriate. Although clinical circumstances, supervisee experience-level, and type of supervisee (resident or different non-physician practitioner types) should influence the extent to which virtual supervision is appropriate, STS recognizes the benefits of continued virtual supervision. During the COVID-19 PHE, virtual supervision proved effective and efficient in many clinical settings with both residents and non-physician practitioners. However, STS does suggest that after the COVID-19 PHE, video may be

necessary in some, but not all, supervising roles. STS recommends that CMS make permanent the interim allowance for virtual supervision even after the conclusion of the COVID-19 PHE.

F. Proposal to Establish New Code Categories
b. Overview of Policies Finalized in CY 2020 for CY 2021

E/M Inherent Complexity Add-on Code

CMS has requested input on what aspects of the code definition for add-on code GPC1X are "unclear", how the Agency might address the concerns, and how CMS could refine its utilization assumptions.

Although CMS indicates that the proposed add-on code, GPC1X (*visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition (add on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*) is not restricting billing by specialty, STS continues to have serious concerns with CMS's proposal to create add-on code GPC1X for office visits. CMS continues to classify GPC1X as a code that they assume will be furnished by certain types of specialties (family medicine, general practice, internal medicine, pediatrics, geriatrics, nurse practitioner, physician assistant, endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonary disease) more than others and have based their utilization and rate setting assumptions using these estimates. However, it is still unclear why this code is needed. CMS has indicated that "the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits." STS disagrees with this premise and feels that the revised and revalued office/outpatient E/M visit codes along with the new prolonged service add-on code are adequate for reporting services provided to patients with single, serious, or complex chronic conditions requiring comprehensive longitudinal and continuous care. The sickest patients are typically already in the hospital and those services would be reported with the hospital inpatient new or subsequent visit codes or other appropriate CPT codes, not the E/M office/outpatient new or established patient visit codes, so the proposed add-on code would not apply to a significant portion of the demographic targeted by CMS. Furthermore, it is still not clear when and how the add-on code should be utilized. The code descriptor for GPC1X is different throughout different sections of the NPRM making it difficult to respond to CMS' request for input on what aspects of the code definition are unclear. In addition, CMS' rationale for implementing the code has shifted over the several years of rulemaking in which the code has been discussed, with CMS itself thus undermining the need for the existence of the code at all.

CMS utilization projections for GPC1X assume the code would be applied to 75% of all office visit claims, costing the Medicare program $3.3 billion annually, which will account for a 3.5% reduction in the conversion factor. This is a 25 point increase in utilization (50% to 75%) from their original estimate in 2020 with no explanation as to why they increased their utilization assumptions. The methodology CMS used to arrive at the 2021 utilization assumptions for code GPC1X should be published prior to implementation of the code.

STS urges CMS to withdraw implementation of GPC1X and begin working with CPT, RUC, and the national medical societies to determine if additional codes are needed to compensate physicians for a specific type of work not covered in the newly revised office/outpatient E/M services or other CPT codes. This collaboration would allow for creation of codes, if needed at all, which are clear and ensure a delineation of work which does not overlap and that is appropriately valued. If CMS decides to implement the code, STS strongly urges CMS to re-examine and lower its 2021 utilization assumptions and provide clear guidance on when and how the code should be used.

Revised CPT 99201 – _99215 Code Time Values

CMS is proposing to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215 beginning January 1, 2021.

The RUC-recommended time values for the office/outpatient E/M visits are based on the "total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time)". The surveys considered the total time spent on the day of the visit, as well as the time spent on any pre- and post-service time occurring within 3 days prior to and 7 days after the visit. The sum of the surveyed components (pre-intra- and post-times) is different than the RUC-recommended total time for the codes.

STS recommends that CMS adopt the RUC-recommended median survey times instead of the component time totals which will retain relativity. The RUC provided an explanation as to why the median total time will not necessarily equal the sum of the median times for each of the three-time (pre-, intra-, post-) periods explaining that the way physician time was captured for the recent office visits was different than the typical survey. As explained by the RUC, since the survey instructed that the time spent 3 days before, the day of and 7 days after the visit, the time responses will vary depending on the physicians work flow where one physician may spend time the day before the encounter and another physician does all the pre-service work the day of the visit. STS supports the RUC recommendation that using time based on the sum of the components does not appropriately capture the physician time for the office visit and that the total time is the appropriate measurement since it uses each individuals total time in determining the median total time.

G. Scopes of Practice and Related Issues
General Feedback

During the COVID-19 PHE, CMS allowed supervision requirements for residents and non-physician practitioners (NPPs) to be provided virtually via audio and video technology. CMS has inquired throughout the 2021 Physician Fee Schedule whether to extend these virtual supervision policies through the end of 2021 or even permanently.

As previously stated, STS supports virtual supervision of residents and NPPs given the appropriate setting and circumstance. STS recommends that CMS establish permanently an opportunity for virtual supervision, depending on the professional judgment of the supervising physicians. Generally, considerations would include:

- Clinical circumstance: Procedural vs. office visit; some procedural visits with higher levels of complexity require in-person supervision
- Experience-level of the supervisee: Depending on the circumstance, less experienced residents or NPPs may benefit from continued in-person supervision
- Type of supervisee provider: resident, type of NPPs
- Type of telecommunications platform: In general video is preferred, but there are likely circumstances in which audio-only is appropriate.

e. Primary Care Exception Policies

During COVID-19, CMS allowed payment in primary care for certain lower and midlevel complexity services provided by residents without the presence of a teaching physician. CMS is considering extending this policy, as well as adding higher level E/Ms (CPT 99204, 99205, 99214, 99215).

STS recognizes that these allowances may be reasonable during the COVID-19 PHE. However, we recommend empirically assessing the impact of these allowances on patient safety before they are continued either temporarily or permanently after the PHE.

H. Valuation of Specific Codes
4. Proposed Valuation of Specific Codes for CY 2021

STS continues to be concerned about CMS treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity. As we have stated in previous comments, it is incorrect and inconsistent to apply intensity to only certain services, and it creates inherent payment disparities in the relativity of valuations in the payment system. CMS' continued practice of applying flawed methodologies (e.g. time ratios, incremental adjustments) or selecting an arbitrary combination of inputs (e.g. intra- or total time, various work RVUs, crosswalks etc.) and applying them to arrive at valuations is also concerning. CMS' selection process uses a vast array of possible mathematical calculations to arrive at an arbitrary value, rather than seeking a valid, clinically relevant relationship that preserves relativity. In this rule, as in the past, CMS does not provide any clinical foundation for the comparison of the surveyed code to their selected crosswalk and reference codes. Instead, it appears that the Agency selects comparison codes solely for their time or time ratio comparisons to support their desired reductions. In comments, CMS commonly dismisses the input from practicing physicians with valid surveys and the rigorous review by the specialty society committees and the magnitude estimation and cross-specialty comparisons that have been conducted by the RUC. As in past comments, STS requests that CMS provide clinical rationale when proposing crosswalks or other methodologies for valuation of services.

(9) Toe Amputation (CPT codes 28820 and 28825)

CMS rejected the RUC-recommended work RVU of 4.10 for CPT code 28820 (Amputation, toe; metatarsophalangeal joint) and are instead proposing a work value of 3.51 using a crosswalk to CPT code 33958 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)). CMS indicates that the proposed reduction is to account for the decrease in the surveyed work time and that they "do not believe that the RUC-

recommended reduction in work RVU from the current value of 5.82 is commensurate with the RUC-recommended 102-minute reduction in total time."

CMS also disagrees with the RUC-recommended work RVU of 4.00 for CPT code 28825 (Amputation, toe; interphalangeal joint) and is proposing to apply the RUC-recommended increment between this code and CPT 28820 to their proposed value for 28820 for a work RVU of 3.41. Again, CMS indicates that they "do not believe" that the RUC-recommended reduction of the work RVU from its current value of 5.37 to 4.00 is commensurate 97-minute reduction in total time recommended by the RUC.

As mentioned above, STS disagrees with CMS' consideration of time alone when considering the RUC-recommended work RVUs for codes with decreased intra-service and/or total times. STS continues to urge CMS to consider the intensity of procedures in addition to time. CMS' proposal to crosswalk the code 28820 to code 33958 is not a rational comparison and it does not account for intensity differences in the procedures. Code 33958 is a percutaneous procedure for repositioning a life-saving ECMO cannula, which includes a same day inpatient hospital visit not typical for 000 day global procedures. While the repositioning of the ECMO cannula does include some inherent risks, the nature of the procedure does not carry similar intensity as a toe amputation. CMS' proposal to use code 33958 as a crosswalk based on time should also take into account the difference in intensity, as the RUC did in their deliberations. Further, it does not appear that CMS considered the change in the global surgical period from a 90 day global to a 000 day global when referencing the decrease in total time for the procedure, which would make sense for a change in the global period and the associated intensity for the procedure. The intra-service time for the procedure did not change. STS feels that the RUC-recommended work RVU of 4.10 based on survey data, which is based on magnitude estimation taking into consideration the time *and intensity* for a procedure is appropriate for this code. STS also supports the RUC-recommended work RVU of 4.00 for code 28825.

STS also disagrees with the CMS' proposal to refine the pre-service clinical labor times to conform to the 000- day global period standards for codes 22820 and 22825. Both codes represent major surgical procedures that are typically performed in a facility setting (98% and 94%, respectively) under general anesthesia. The change in global period for these procedures does not change the fact that they represent major surgical procedures that require the same amount of clinical labor time as any other major surgical procedure with a 090-day global period. There are several examples of major surgical codes with 000-day global periods where the 090-day global major surgery pre-service clinical labor times standard for the facility setting have been accepted.

(13) Atrial Septostomy (CPT codes 33XX0, 33XX1, 33XX2)

The atrial septostomy codes were updated to incorporate image guidance and expand their application to more complex procedures not previously performed when the original septostomy codes (92992 and 92993) were created. CMS accepted the RUC-recommended work RVUs for CPT codes 33XX0 (Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (eg, Rashkind, Sang-Park, balloon, cutting balloon, blade)) and 33XX1 (Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan

fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt), which will replace codes two codes (92992 and 92993) that will be deleted. CMS did not accept the RUC-recommended work RVU of 10.50 with 60 minutes of intra-service time for CPT add-on code 33XX2, (Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)), which may be reported with CPT code 33XX1. Instead, CMS is proposing a work RVU of 8.00 for add-on, which is the 25th percentile value from the survey and is similar to the valuation of CPT reference ode 93592 (Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)), which has 60 minutes of intra-service time and a work RUV of 8.00.

STS agrees with CMS' proposal to accept the RUC-recommended work RVUs for two of the new codes (33XX0 and 33XX1). STS disagrees with CMS' proposal to base the value on the identical time of 93592, which is flawed because it ignores that the typical patient undergoing procedure 33XX2 is a small child or infant. This increases the complexity significantly compared to the adult patient for 93592. It also ignores the recognized, significantly increased intensity and complexity of placing a stent within the beating heart which carries a risk of the stent embolizing from the intended location. Although 93592 also involves placement of a device or coil within the beating heart, all devices and coils used for repairing a paravalvular leak are less challenging to retrieve, remove, and/or reposition should they move from their intended location. In contrast, once an intracardiac stent is delivered, if not perfectly positioned, the only recourse is emergent open-heart surgery. However, this would occur in a patient for whom surgery was already deemed too high a risk, even in ideal, elective circumstances. Other CPT codes for each of the additional stent scenarios, are purely intravascular and the repositioning for delivery of the additional stent represents less intense/complex work. For intracardiac purposes, 33XX2 is not intended as an extension of an initial stent, which is covered entirely by 33XX1. The lesions covered by the work for 33XX2 are entirely distinct from that covered by 33XX1
and require considerable work to reposition all necessary catheters and wires for the additional stent procedure.

The RUC-recommended median work RVU of 10.50 accounts for the difference in intensity between the survey and the reference code. At the 10.50 value, the add-on 33XX2 has a calculated intraservice intensity that is higher than the key reference service but lower than 33XX1 for the placement of the initial stent, which is appropriate within the family of codes and relative to the reference codes. STS urges CMS to finalize the RUC-recommended median work RVU of 10.50 from the survey.

*(*43) Ventricular Assist Device (VAD) Interrogation (CPT code 93750)

CPT code 93750, (Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report) currently has a work RVU of 0.92 with 30 minutes of intraservice time. This code was identified through the Relativity Assessment Workgroup (RAW) screen for Medicare utilization of over 10,000 claims in a year with an increased in volume by 100 percent between 2012 to 2017. The RUC

survey supported 6 minutes preservice time, 10 minutes intraservice time, 7 minutes immediate post-service time and 23 minutes of total time and the 25th percentile surveyed work RVU was 0.96. The RUC-recommended a work RVU of 0.96 based on a crosswalk to CPT code 78598 (Quantitative differential pulmonary perfusion and ventilation (eg, aerosol or gas), including imaging when performed) which has a work RVU of 0.85 work RVU, 5 minutes of preservice time, 10 minutes of intraservice time, 9 minutes of immediate post-service time, and total time of 24 minutes. CMS is proposing a work RVU of 0.75 based on a crosswalk to code 93289 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements), with 0.75 work RVUs and 5 minutes of preservice time, 10 minutes of intraservice time, 8.5 minutes of immediate post-service time, and total time of 23.5 minutes

STS worked with other specialty societies to survey code 93750. The survey generated results that would have led to an increased work RVU valuation, which the societies did not deem as acceptable given the reduction in service time. The societies noted significant changes in the service from its initial valuation, including a change in the dominant specialty. The service was originally provided predominately by surgeons, now the service is most commonly used by heart failure cardiologists to calibrate care and a failure of the existing inputs to delineate between service period increments. These changes make it impossible to know the exact driver of the change in time.

The societies and the RUC agreed that a modest reduction by crosswalk to a service with similar service times was appropriate, and selected code 78598 which they felt appropriately reflected the time and intensity for the procedure. CMS, in essence, goes through the same exercise but proposes a different code (93289) with similar times that has an even lower value. This is a service the societies considered as a crosswalk but abandoned because it does not involve device programming, which the VAD service does, as the device speed is frequently adjusted to optimize performance. That realization prompted search for the crosswalk ultimately recommended by the RUC that is appropriately slightly higher than the defibrillator interrogation service.

While both the ICD and VAD patients are ill, VAD patients have heart failure that has deteriorated to such a degree that a mechanical pump has been inserted into their chest to support their heart while they await a transplant or to improve the quality of their remaining life. The underlying illness is different, and the RUC-recommended, slightly higher crosswalk appropriately recognizes that difference. As such, STS recommends CMS accept the RUC-recommended work RVU of 0.85 for 93750 which incorporates an appropriate increment above the crosswalk value proposed by CMS.

III Other Provisions of the Proposed Rule

H. Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

CMS is proposing not to require that the physician who establishes the plan of care a mandatory form or specific manner of frequency notifications require the regarding the manner or frequency of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, provide the patient with a specific notification.

STS agrees that physicians already routinely discuss infusion therapy options with their patients and annotate these discussions in their patients' medical records. STS agrees with CMS that it is not necessary to create a mandatory form or require a specific manner or frequency of notification of options available for infusion therapy prior to establishing a home infusion therapy plan of care.

J. Proposal to Remove Selected National Coverage Determinations (NCDs)

CMS previously established a process for removing outdated National Coverage Determinations (NCDs) (i.e., 10 years or older), allowing Medicare Administrative Contractors (MACs) to determine coverage previously covered by an NCD. CMS proposes to identify and remove NCDs that are not reflective of current medical practice. CMS indicates that eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare and that coverage determinations will be made by the MACs. CMS is proposing to remove 9 NCDs under the rulemaking process, which the agency believes is appropriate based on the Supreme Court's ruling on Azar v. Allina Health Services.

While we understand that it does not make sense for CMS to maintain national coverage for all procedures in perpetuity, STS is concerned with what appears to be a general effort to move away from national coverage to local coverage. NCDs are deployed when disparate coverage policies across contractors exist or are expected, when complex or novel or resource-intensive services are under consideration, or when concerns about overutilization/misutilization exist.

We do not agree with the statement that "local contractor discretion to make coverage decisions better serves the needs of the Medicare population," in all cases. Inconsistent and inaccurate coverage policies create access limitations and disparities that impose significant administrative burden on providers and stress on seriously ill patients. Sometimes patients are referred to another state where coverage is more appropriate and allows a therapy the physician and patient agree is necessary. However, that type of travel may not be an option for all Medicare beneficiaries. Although local factors may be particularly relevant in discrete cases and should be evaluated against the standards outlined in sections 1862(l) and 1860(f) of the Social Security Act, arbitrary time limitations, for example, are not reasonable standards for evaluating the utility of an NCD.

In addition, CMS may consider that quality data collected as a part of an NCD is an effective way to evaluate and maintain quality care, especially when new technology is brought to market and covered in previously unstudied populations or when quality metrics need require a certain sample size to be statistically significant. In general, we feel that CMS should focus on optimizing appropriate use of NCDs rather than minimizing their use.

IV. Quality Payment Program
3. MIPS Program Details
a. Transforming Merit-Based Incentive Payment System (MIPS): MIPS Value Pathways (MVP)

In the CY 2020 PFS final rule (84 FR 62946), CMS finalized the definition of MIPS Value Pathways (MVP). CMS introduced the MVP framework in an effort to create a more cohesive participation experience across the four MIPS performance categories and better prepare clinicians for transitioning to alternative payment models. Although CMS is currently presenting MVPs as a voluntary option, CMS suggests that

all MIPS eligible clinicians could be required to participate in MIPS either through an MVP or APM Performance Pathway (APP) in the future.

CMS originally intended to apply the MVP framework in the 2021 performance year. However, due to the COVID-19 PHE, CMS proposes delaying transition to MVPs until at least the 2022 performance year. At the same time, CMS expresses its commitment to this framework and proposes limited updates to the MVP guiding principles and development criteria.

STS provided detailed feedback to the MVP program in its comment letter on the CY 2020 PFS proposed rule. In response to the current 2021 PFS proposed rule, STS reiterates that while we support CMS' effort to reduce clinician burden and to offer a pathway for more clinicians to transition to alternative payment arrangements, we have strong concerns that the MVP framework lacks the specificity and applicability to truly affect change. By attempting to fit the MVP model into the current MIPS framework, CMS fails to provide a more meaningful and less burdensome participation pathway for specialists or to provide a practical glide path to APMs. As we noted last year, it is critical that CMS recognize multi-category measures that simultaneously address two or three MIPS performance categories, such as quality measures reported to qualified clinical data registries that may also earn a clinician credit for the Improvement Activities or Promoting Interoperability categories.

STS also urges more transparency and standardization in the MVP vetting process. Although CMS points to stakeholder input and feedback opportunities, collaborative dialogue has been limited. STS also encourages CMS to become more open to innovative ideas regarding the evaluation of quality and value when presented by specialty societies, as well as ensuring that appropriate experts participate on any vetting panels. It seems as though many ideas that stray too far from status quo are not given serious consideration or feedback. These are missed opportunities to listen to actual providers who understand how to effectively move clinicians toward value while also keeping the program relevant to clinical realities. STS suggests that CMS pilot test the framework in practices that treat a single condition, focus on a relatively homogenous patient population, and have existing measures and activities. Over time, CMS can begin to develop more complex MVPs that recognize team-based approaches to care and/or rely on more innovative measures.

STS has the following specific feedback related to MVPs:

- STS requests clarity on the role of QCDR measures in MVPs
- STS requests clarity on benchmarking and scoring:
    - Will participants in a single MVP only be compared to others reporting that MVP or to the broader MIPS eligible clinician population reporting on measures within that MVP?
- How will CMS use MVPs to promote subgroup reporting if there is currently no mechanism to report that way under MIPS?
- STS is concerned by CMS statements that suggest that all measures and activities included in an MVP have the same denominator. In most cases, it would not be clinically feasible to meet this requirement due to the reality of patient case mix in clinical settings and the existence of measure exceptions and exclusions that are not necessarily consistent across related measures.
- STS encourages CMS to reconsider the current set of total per capita cost measures used under MIPS, which are not actionable nor appropriate for clinician-level accountability.

c. MIPS Performance Category Measures and Activities

For payment year 2021, CMS proposes decreasing the weight of the Quality performance category, while increasing the Cost performance category weight:

Payment Year 2020:	Payment Year 2021:
• Quality: 45% • Cost: 15% • Promoting Interoperability: 25% • Improvement Activities: 15%	• Quality: 40% (5% decrease from PY 2020) • Cost: 20% (5% increase from PY 2020) • Promoting Interoperability: 25% • Improvement Activities: 15%

STS understands that a gradual shift in the weight of the Quality category to the Cost category is intended to prepare clinicians for 2022, when CMS is required to weight each of those categories at 30%. However, we recommend against a weight redistribution during the COVID-19 PHE. In 2021, clinicians will be continuing to focus efforts on treating patients with COVID-19, adjusting to unusual care volumes and atypical case presentations as a result of pandemic-related delayed care, and stabilizing health care financing due to months of pandemic impact. Given the highly unusual clinical and practice circumstances, now is not the time to ratchet up the Cost category as an indicator of performance. Cost increases for staffing and equipment due to COVID-19 may not reflect the usual and customary costs of providing care. This would adversely impact regions hard hit by the pandemic.

Additionally, the Cost measures have existing flaws that will require time and continued stakeholder and CMS collaboration to improve effective measurement of performance. As currently designed, the MIPS program has created silos between quality and costs, which does not allow any true measure of the relationship since the cost measures are not directly tied to any quality monitoring. Clinicians have far more direct control over quality measures than they do over the current set of cost measures. Given the instability in health care financing due to the pandemic, a shift away from quality measures introduces even more uncertainty into clinician performance.

STS strongly urges CMS to retain the 15% weight for the Cost category in 2021, and to remain flexible with this category due to ongoing issues related to existing cost measures.

(d) Selection of MIPS Quality Measures

CMS proposed an updated list of MIPS quality measures. Proposed changes include the addition of new measures, updates to specialty sets, the removal of existing measures, and substantive changes to existing measures. The 2021 performance period includes a total of 206 MIPS quality measures. CMS states that the overarching goal in proposing this revised list is to reduce the number of process measures within the measure set.

STS reiterates our previously articulated concerns about quality measures in the MIPS program. Specialty societies and clinicians are uniquely qualified to choose meaningful measures that demonstrate quality to their colleagues and their patients. Measures that are topped out are still meaningful to clinicians and patients and demonstrate quality care. The need to measure quality improvement should not replace the need to demonstrate ongoing excellence of care. For example, previously the mortality measure for Lung Cancer lobectomy was dropped while process measures for

antibiotics remain. Clearly patients and providers understand the importance of antibiotics but are far more concerned with survival.

STS strongly encourages CMS to reward quality as measured by performance on those measures most meaningful to patient outcomes specific to cardiothoracic surgery. Although not all of these meaningful measures have room for clinicians to improve performance, they do provide the most relevant data regarding successful patient outcomes and therefore play a key role in maintaining high quality care and informing patient medical decision-making.

CMS continues to include measure #317 Screening for High Blood Pressure and Follow-Up Documented in the Thoracic Specialty Set.

STS has repeatedly expressed concern to CMS regarding the inclusion of measure #317 Screening for High Blood Pressure and Follow-Up Documented in the Thoracic Surgery Specialty Set. STS does not believe this measure is appropriate for the Thoracic Surgery Specialty Set as long term blood pressure management is conducted by members of the care team other than the cardiothoracic surgeon. Aligned with our previous comments submitted to CMS for the CY 2019 and 2020 proposed rules, STS requests removing measure #317 Screening for High Blood Pressure and Follow-Up Documented from the Thoracic Surgery Specialty Set.

CMS proposes to use performance period, not historical, benchmarks to score quality measures for the 2021 performance period due to concerns that the COVID-19 PHE could skew benchmarking results.

STS agrees that performance period benchmarks are more appropriate for quality measurement if they represent current national practice. Furthermore, STS recommends using national benchmarks such as those in the STS National Database which capture more than 93% of cardiac surgery cases.

(2) Qualified Clinical Data Registries (QCDR)

CMS proposes new requirements for QCDR data validation audits, targeted audits, measures, and measure testing requirements.

The new data validation proposal includes codifying § 414.1400(b)(2)(iv) and (v) requirements that, beginning with the 2023 MIPS payment year as a condition of approval, each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits. CMS further outlines extensive obligations for these audit obligations in the proposed rule.

Additionally, CMS proposes modifying QCDR measure testing policy and adding testing policies for QCDR measures that are being considered for inclusion in MVPs:

- *CMS proposes the inclusion of QCDR measures in MVPs, at CMS discretion, beginning in the 2024 MIPS payment year.*
- *CMS proposes to both further modify its QCDR measure testing policy generally and add testing policies for QCDR measures that are being considered for inclusion in MVPs. QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year.*

Additionally, these measures which were approved for the preceding MIPS performance year with face validity, would be required to be fully tested prior to being self-nominated for any subsequent performance periods in order to be considered for inclusion in the MIPS program.

The STS National Database was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The Database has four components—the STS Adult Cardiac Surgery Database, the STS General Thoracic Surgery Database, the STS Congenital Heart Surgery Database, and the STS Intermacs Database (mechanical circulatory support), as well as the STS/ACC TVT Registry (transcatheter aortic valve replacement and transcatheter mitral valve repair). Not only does the STS National Database contain decades of clinical outcomes data, the Database is also a designated Qualified Clinical Data Registry.

As a QCDR, STS and the National Database have long been active stakeholders in CMS QCDR policies. Unfortunately, STS has identified a pattern of increasingly burdensome requirements placed on QCDRs. Given the decades of experience the STS National Database has in collecting and tracking quality data, we are specifically frustrated with CMS' increasingly burdensome and unreasonable requirements for QCDRs that place an almost prohibitive difficulty on maintaining QCDR status. These QCDR policies, as a whole, have eliminated important measures for cardiothoracic surgeons and placed overly burdensome audit and data submission requirements on QCDRs. This means that as measures have become less clinically relevant to patient outcomes, CMS has asked QCDRs to pay for and perform increasingly onerous audits. At the same time, CMS payment policies are pushing more and more cardiothoracic surgeons into hospital employment. Many hospital-employed surgeons are not even aware that their employers are reporting on their behalf, under their specific TIN, using measures that are completely unrelated to cardiothoracic surgery. As the number of STS members participating in MIPS quality reporting continues to decline, the value proposition of QCDRs is diminishing, which seems antithetical to the Congressional intent of this reporting mechanism.

STS has participated in physician quality reporting since its inception. The use of existing real world clinical registry data for quality measurement is crucial to reduce provider burden and provide quality measures that are meaningful to patients and providers. Unfortunately, the QCDR program has become more demanding, complicated, and costly making it increasingly difficult for registries to continue participation. STS presents the following specific concerns to CMS:

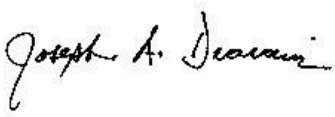
- Mandating QCDR reporting of Promoting Interoperability (PI) measures and Improvement Activities (IA) shift additional burden and expense to QCDRs
- *CMS is proposing to establish specific data validation requirements for QCDRs:*
    - STS reiterates that QCDRs have rigorous internal quality data standards which should be recognized and accepted by CMS. The proposed additional requirements are unnecessarily duplicative, burdensome, and costly.
- *CMS is proposing that QCDRs conduct data validation audits, with specific obligations, on an annual basis:*
    - The STS National Database hires an external auditing firm to conduct audits for 10% of participating sites at significant cost to the organization. Provider level audits have added to this financial burden, are time consuming, and do not enhance overall data quality or validity. STS opposes these additional requirements.

- *CMS is proposing that QCDRs would also conduct a targeted audit if errors are identified during the data validation audit.*
    - Given the rigorous internal quality data standards already present in the STS registries, STS opposes this proposal as it brings additional and unwarranted burden to the Society and providers.
- *CMS proposes additional measure testing requirements beginning with the 2022 performance period. The proposal includes requiring QCDR measures to be fully tested at the clinician level to be considered for inclusion in an MVP.*
    - Although STS supports rigorous measure testing, we believe the level (clinician, facility, or group) should be decided by QCDR statisticians familiar with sample sizes and populations. STS anticipates that the proposed requirements for additional measure testing will add a level of complexity and cost that may drive QCDRs and registries out of the program.

*****

STS appreciates the opportunity to share this feedback with CMS. Should you have any questions about our comments or concerns, please contact STS Director of Government Relations Courtney Yohe at 202-787-1222 or cyohe@sts.org.

Sincerely,



Joseph A. Dearani, MD
President

Appendix A

CPT Code	Anticipated Specialty (2021)	STS Proposed Revision
33251	THORACIC SURGERY	CARDIAC SURGERY
33606	THORACIC SURGERY	CARDIAC SURGERY
33608	THORACIC SURGERY	CARDIAC SURGERY
33611	THORACIC SURGERY	CARDIAC SURGERY
33612	THORACIC SURGERY	CARDIAC SURGERY
33617	THORACIC SURGERY	CARDIAC SURGERY
33619	THORACIC SURGERY	CARDIAC SURGERY
33620	THORACIC SURGERY	CARDIAC SURGERY
33621	THORACIC SURGERY	CARDIAC SURGERY
33622	THORACIC SURGERY	CARDIAC SURGERY
33645	THORACIC SURGERY	CARDIAC SURGERY
33647	THORACIC SURGERY	CARDIAC SURGERY
33660	THORACIC SURGERY	CARDIAC SURGERY
33665	THORACIC SURGERY	CARDIAC SURGERY
33670	THORACIC SURGERY	CARDIAC SURGERY
33675	THORACIC SURGERY	CARDIAC SURGERY
33676	THORACIC SURGERY	CARDIAC SURGERY
33677	THORACIC SURGERY	CARDIAC SURGERY
33684	THORACIC SURGERY	CARDIAC SURGERY
33688	THORACIC SURGERY	CARDIAC SURGERY
33690	THORACIC SURGERY	CARDIAC SURGERY
33692	THORACIC SURGERY	CARDIAC SURGERY
33694	THORACIC SURGERY	CARDIAC SURGERY
33697	THORACIC SURGERY	CARDIAC SURGERY
33702	THORACIC SURGERY	CARDIAC SURGERY
33710	THORACIC SURGERY	CARDIAC SURGERY
33720	THORACIC SURGERY	CARDIAC SURGERY
33722	THORACIC SURGERY	CARDIAC SURGERY
33724	THORACIC SURGERY	CARDIAC SURGERY
33726	THORACIC SURGERY	CARDIAC SURGERY
33730	THORACIC SURGERY	CARDIAC SURGERY
33732	THORACIC SURGERY	CARDIAC SURGERY
33735	THORACIC SURGERY	CARDIAC SURGERY
33736	THORACIC SURGERY	CARDIAC SURGERY
33737	THORACIC SURGERY	CARDIAC SURGERY
33750	THORACIC SURGERY	CARDIAC SURGERY
33755	THORACIC SURGERY	CARDIAC SURGERY

Appendix A

33762	THORACIC SURGERY	CARDIAC SURGERY
33764	THORACIC SURGERY	CARDIAC SURGERY
33766	THORACIC SURGERY	CARDIAC SURGERY
33767	THORACIC SURGERY	CARDIAC SURGERY
33768	THORACIC SURGERY	CARDIAC SURGERY
33770	THORACIC SURGERY	CARDIAC SURGERY
33771	THORACIC SURGERY	CARDIAC SURGERY
33774	THORACIC SURGERY	CARDIAC SURGERY
33775	THORACIC SURGERY	CARDIAC SURGERY
33776	THORACIC SURGERY	CARDIAC SURGERY
33777	THORACIC SURGERY	CARDIAC SURGERY
33778	THORACIC SURGERY	CARDIAC SURGERY
33779	THORACIC SURGERY	CARDIAC SURGERY
33780	THORACIC SURGERY	CARDIAC SURGERY
33781	THORACIC SURGERY	CARDIAC SURGERY
33782	THORACIC SURGERY	CARDIAC SURGERY
33783	THORACIC SURGERY	CARDIAC SURGERY
33786	THORACIC SURGERY	CARDIAC SURGERY
33788	THORACIC SURGERY	CARDIAC SURGERY
33800	THORACIC SURGERY	CARDIAC SURGERY
33802	THORACIC SURGERY	CARDIAC SURGERY
33803	THORACIC SURGERY	CARDIAC SURGERY
33813	THORACIC SURGERY	CARDIAC SURGERY
33814	THORACIC SURGERY	CARDIAC SURGERY
33820	THORACIC SURGERY	CARDIAC SURGERY
33822	THORACIC SURGERY	CARDIAC SURGERY
33824	THORACIC SURGERY	CARDIAC SURGERY
33840	THORACIC SURGERY	CARDIAC SURGERY
33845	THORACIC SURGERY	CARDIAC SURGERY
33851	THORACIC SURGERY	CARDIAC SURGERY
33852	THORACIC SURGERY	CARDIAC SURGERY
33853	THORACIC SURGERY	CARDIAC SURGERY
33920	THORACIC SURGERY	CARDIAC SURGERY
33922	THORACIC SURGERY	CARDIAC SURGERY
33926	THORACIC SURGERY	CARDIAC SURGERY
35182	THORACIC SURGERY	CARDIAC SURGERY
96440	THORACIC SURGERY	HEMATOLOGY ONCOLOGY
33991	CARDIAC SURGERY	INTERVENTIONAL CARIOLOGY
31781	THORACIC SURGERY	OTOLARYNGOLOGY

Appendix A

43116	THORACIC SURGERY	OTOLARYNGOLOGY
39503	THORACIC SURGERY	PEDIATRIC
43313	THORACIC SURGERY	PEDIATRIC
43314	THORACIC SURGERY	PEDIATRIC