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Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-FC, P.O. Box 8013
Baltimore, MD 21244-8013

Re: [CMS-5517-P] Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentives under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models Proposed Rule

Dear Acting Administrator Slavitt,

On behalf of The Society of Thoracic Surgeons (STS) I write to submit comments on the Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentives under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models Proposed Rule. 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.

One of the foundational principles driving the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was the harmonization and simplification of the various reporting requirements heaped upon Medicare providers. While this proposed rule does attempt to align physicians' reporting requirements, the Quality Payment Program (QPP), as outlined, is hopelessly complicated. Physicians seeking to succeed under the new program will have a very difficult time understanding how they can actively work to increase their MIPS composite scores. Further, as the program changes over time, those goals will become moving targets. Add to this the fact that providers will be rewarded or penalized based on their performance two years prior, using benchmarks calculated from baseline data collected two years prior to that, and it becomes very likely that all MIPS participants will feel disenfranchised by the new payment system, and unable to control their own destinies. In the end, they will fail.

Because of the complexities of the MIPS program, STS, a specialty society representing cardiothoracic surgeons, was prepared to offer a physician-focused payment model (PFPM) to both the Physician-focused Payment

Model Technical Advisory Committee (PTAC) and the Center for Medicare and Medicaid Innovation (CMMI) for consideration and implementation. Because of our unique resource – the STS National Database – we believed that we would be able to demonstrate to the Centers for Medicare and Medicaid Services (CMS) a payment model capable of rewarding physicians for increasing the quality of care they provide and reducing resource use. Unfortunately, that pathway has also become very complicated and impossible to navigate within an unrealistically aggressive time frame. Our society supports policies and activities that enhance the abilities of our surgeons to deliver the highest quality and most cost efficient value based care to our patients. We hope physician-focused payment models will be an opportunity to demonstrate and codify that commitment.

Further, we ask CMS to prioritize stakeholder participation in the development of Advanced APMs that are relevant to specialty medicine. Congress created the PTAC to both improve transparency at CMMI and increase the variety, efficacy and number of APMs, in hopes of maximizing the number of physicians and medical specialties able to participate. We believe that we are uniquely situated to demonstrate how the Medicare program might accurately reimburse cardiothoracic surgeons for improved health care quality and patient outcomes. We hope that the final rule will address many of the barriers to that future collaboration. Furthermore, we ask CMS to prioritize the testing and implementation of stakeholder-driven APMs, specifically those that are relevant to specialty medicine.

Although we make specific recommendations about the QPP below, we encourage CMS to simplify its interpretation of the MACRA statute wherever possible. We also hope to work with CMS and Congress to ensure that providers have enough time to understand and implement the new QPP before performance measurement commences.

General MIPS Program Input

Timeline and Reporting Period

For 2019 and subsequent years, CMS proposes that the performance period under MIPS would be the calendar year 2 years prior to the year in which the MIPS adjustment is applied. Therefore, the performance period for the first MIPS payment adjustment in 2019 would be January 1, 2017 through December 31, 2017.

STS opposes CMS' proposed performance period for MIPS, particularly for the first year of MIPS. The final rule setting forth the requirements for the 2019 MIPS payment adjustment is not expected until November 2016. This would only provide two months or less (mostly occurring during the holiday season) for us to become versed in the requirements for the first year of MIPS measurement and educate our members prior to the start of the proposed performance period for the 2019 MIPS payment adjustment (January 1, 2017). We note that, while the proposed requirements of MIPS carry certain aspects of other CMS initiatives with which we are familiar (such as the Physician Quality Reporting System (PQRS), there are still several changes being proposed that represent stark departures from currently existing CMS quality programs. For example, MIPS will now score performance in four separate categories to determine an eligible clinician's payment, including a new clinical practice improvement activity

(CPIA) performance category. There are also other proposed changes related to reporting options and requirements, reporting periods, and eligible and exempt professionals. **Therefore, STS urges CMS to delay the start of the performance period for 2019 MIPS adjustments until July 1, 2017 at the earliest**. A July 1, 2017 start date for the performance period for the 2019 MIPS payment adjustment is consistent with the reporting period of the first year of PQRS (then the Physician Quality Reporting Initiative or PQRI) that incorporated a July 1st start date. Further, we urge CMS to be more transparent about what administrative limitations are prohibiting the timely processing of physician performance. Many private payors are able to implement performance improvement programs on a much timelier basis. In order for the physician community to help CMS to address these concerns, we need to know what specific challenges CMS is facing.

Feedback Reports

The first physician performance feedback is due on July 1, 2017, which is prior to CMS having received any MIPS data. Therefore, CMS proposes to initially provide feedback to MIPS eligible clinicians who are participating in MIPS using historical data set(s), as available and applicable. For example, CMS could provide physicians with CY 2015 or CY 2016 quality and resource use data, despite the fact that the MIPS program would not have been in place at the time the data were collected. As the program evolves, CMS may consider providing performance feedback of clinical and financial performance on a more frequent basis, such as quarterly.

While STS supports the proposal to provide initial feedback on July 1, 2017 based on historical data for the quality and resource use performance categories, we encourage CMS to look for ways to provide feedback based on timelier data in the future. We believe one way CMS can achieve more timely feedback is by collecting data by third party data submission vendors on a more frequent basis (such as a quarterly). CMS has provided data for the Durable Medical Equipment demonstration in a much more timely fashion (every three-six months) so that participants in the demo could react to the CMS measurement on which they were being evaluated. We urge CMS to adopt the same infrastructure reporting system that existed for this demo and currently exists under the Bundled Payments for Care Improvement (BPCI) program so that providers can understand their performance in a much more relevant timeframe.

CMS seeks comments on whether it should include first year measures (meaning new measures that have been in use for less than 1 year, regardless of submission methods) in performance feedback.

While CMS notes concerns regarding the usefulness and usability of first year measures in MIPS feedback reports, STS believes that CMS should provide information on first year measures in the performance feedback. While CMS may be unsure how to analyze first year measures, we believe it is important for CMS to provide as much data as possible in the feedback reports, as long as such data is not shared publically or used to evaluate performance. Further, CMS may consider gradually incorporating new measures into a provider's overall performance score over a period of years.

Before CMS considers adding CPIA and advancing care information (ACI) data to the performance feedback, CMS would like to engage in stakeholder outreach to understand what data fields might be helpful and usable for MIPS eligible clinicians.

STS welcomes the opportunity to provide feedback now and in the future regarding potential data fields for the feedback reports on the CPIA and ACI performance categories. Regardless of what information is included in the feedback reports for both the CPIA and ACI performance categories, we stress that the data need to be presented in a way that is both easily accessible, and understandable. We also suggest that CMS issue an ACI experience report similar to the annual PQRS Experience Report with as much information as possible, including reporting experiences by specialty.

For the CPIA category, CMS could include information on how many and which activities were completed in the CPIA performance category; the method of data submission used to submit CPIA information; and, in the future, information on improvement relative to prior years. In addition, either as part of the feedback reports or in a CPIA experience report similar to the annual CMS Experience Report, CMS should provide cumulative data about which CPIAs are being reported across MIPS as well as within each specialty designation.

For the ACI performance category, CMS could include information on whether each objective was met/not met for the base score; performance data on the objectives being assessed for the performance score; and whether an eligible clinician or group earned bonus points for each measure reported under the Public Health and Clinical Data Registry Reporting objective other than the Immunization Registry Reporting measure.

Finally, we note our current frustration over our members' difficulty accessing feedback reports, particularly the Quality and Resource Use Reports related to the Value Modifier. Currently, only certain registered staff have the ability to access feedback reports, and the process to do so is tedious. **We request that CMS work to make feedback reports more accessible in the future. Any individual, whether participating as an individual eligible clinician or as part of a group, should be able to easily access feedback reports. In particular, eligible clinicians that are part of a group should be able to access feedback reports independently.**

Weight Reassignments

In instances where a performance category does not apply to a MIPS eligible clinician or group, CMS proposes to assign a weight of zero to the performance category and redistribute the weight for that performance category or categories. CMS proposes to reweight the performance categories for MIPS eligible clinicians when there are not sufficient measures and activities applicable and available to them. If the MIPS eligible clinician does not receive a resource use or ACI performance category score, and has at least three scored measures (either submitted measures or those calculated from administrative claims) in the quality performance category, CMS proposes to reassign the weights of the performance categories without a score to the quality performance category. CMS also proposes an alternative that does not reassign all the weight to the quality performance category, but rather reassigns the weight proportionately to

each of the other performance categories for which the MIPS eligible clinician has received a performance category score. If the MIPS eligible clinicians have fewer than three scored measures in the quality performance category score, then CMS proposes to reassign the weights for the performance categories without scores proportionately to the other performance categories for which the MIPS eligible clinician has received a performance category score.

STS supports CMS' proposal to assign a weight of zero for performance categories that do not apply to an eligible clinician or group. In addition, in the event CMS would need to reassign weight from a performance category or categories, **STS supports CMS' proposal to reassign the weights of the performance categories without a score to the quality performance and CPIA categories**. Since the quality performance category, which replaces PQRS, contains proposed requirements for which we are most familiar, we believe it is reasonable to reassign performance category weights to the quality performance category.

Third Party Data Submissions

In addition to the new submission requirements CMS proposes for each of the four performance categories, CMS proposes to make several changes to third party vendor requirements, such as qualified clinical data registries (QCDRs) participating in MIPS.

We note that keeping up with the new requirements for the four performance categories will already be a huge undertaking. Making significant changes to the QCDR option as it is currently established in PQRS may overburden QCDRs and other third party vendors. In addition, we request that CMS help us ensure that the data submitted are accurate, particularly as we move towards having eligible clinicians being scored based on performance. The data received from electronic health records (EHRs) have been particularly problematic, as these data have been historically inaccurate, unaudited, and potentially unreliable. We urge CMS to concentrate on establishing reporting criteria for EHRs and monitor the submission of accurate data through the use of testing tools that could be used prior to the submission timeframe. In addition, providers may be practicing at multiple institutions that use different EHRs. The lack of interoperability of EHRs and harmonized data definitions and specifications is immensely problematic not only for the individual providers in MIPS but to the CMS as well. The integrity of the data infrastructure for the entire MIPS program is at risk if multiple EHRs that lack interoperability are used as reporting mechanisms.

CMS proposes a QCDR self-nomination period from November 15, 2016 until January 15, 2017. For future years of the program, starting with the 2018 performance period, CMS proposes to establish the self-nomination period from September 1 of the prior year until November 1 of the prior year.

STS opposes the proposed deadlines for QCDR self-nomination of January 15, 2017 for the 2017 performance period and November 1 for the 2018 performance period and beyond. As we stated earlier regarding our concerns with the proposed performance period for the 2019 MIPS payment adjustment, CMS expects to issue a final rule providing requirements for the QPP in November 2016. For the first year of MIPS, we do not believe that QCDRs should be

expected to read, understand, and submit a request for self-nomination within 3 months of the issuance of a final rule. We request that CMS provide QCDRs with additional time to complete the self-nomination process. Specifically, if CMS finalizes a performance period for the 2019 MIPS payment adjustment of January 1, 2017 through December 31, 2017, we request that CMS extend the QCDR self-nomination deadline to March 31, 2017.

CMS proposes that a QCDR must provide the following information to the agency at the time of self-nomination to ensure that QCDR data is valid:

- *MIPS performance categories (that is, categories for which the entity is self- nominating. For example, quality, ACI, and/or CPIA).*
- *Describe the method that the entity will use to accurately calculate performance data for CPIA and ACI based on the appropriate parameters or activities.*

STS requests that CMS not *require* that a QCDR be able to submit data for performance categories other than quality.

In addition, CMS proposes that a QCDR must perform the following functions:

- *At the time of submission, for measures under the quality performance category and as proposed at §414.1400(a)(4)(i), if the data is derived from certified EHR technology, the QCDR must be able to indicate this data source*

  STS opposes this proposal. Only some of the data we receive are derived from an EHR. Further, these data are manually extracted and not automatically populated from EHRs. It would be difficult to require QCDRs to parse out which data fields are populated from EHRs. The value of a QCDR is that it is an objective, systematic and centralized registry available to multiple providers each of whom may be using many different EHRs if they practice at multiple facilities. Additionally, those EHRs may change from one year to the next depending upon individual institutional changes and/or site of practice changes for individual providers. The requirement to cite the various EHR source(s) for each EP adds a remarkable amount of complexity and administrative workload.

- *Provide timely feedback, at least 6 times a year, on all of the MIPS performance categories that the QCDR will report to CMS. That is, if the QCDR will be reporting on data for the CPIA, ACI, or quality performance category, all results as of the feedback report date should be included in the information sent back to the MIPS eligible clinician. The feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the QCDR reports. The QCDR is only required to provide feedback based on the MIPS eligible clinician's data that is available at the time the feedback report is generated.*

  STS opposes CMS' proposal to increase the frequency at which QCDRs must distribute feedback reports to 6 times a year. STS recognizes the value of providing real-time feedback and we are working through our QCDR to implement interactive

dashboards that would provide more actionable and timely data to participants. However, increasing the feedback requirement to 6 times a year is, at this point in time, too big of an administrative and analytic burden. **We request that CMS maintain the current requirement of providing feedback reports at least 4 times a year.**

- *Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the QCDR, has authorized the QCDR to submit quality measure results, CPIA measure and activity results, ACI objective results and numerator and denominator data and/or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation. This documentation must be obtained at the time the MIPS eligible clinician or group signs up with the QCDR to submit MIPS data to the QCDR and must meet the requirements of any applicable laws, regulations, and contractual business associate agreements. Groups participating in MIPS via a QCDR may have their group's duly authorized representative grant permission to the QCDR to submit their data to CMS. If submitting as a group, each individual MIPS eligible clinician does not need to grant their individual permission to the QCDR to submit their data to CMS.*

  STS requests that CMS maintain the current requirement to obtain and keep on file signed documentation for 7 years as currently required under PQRS.

CMS proposes that QCDRs be required to agree that data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent of the total number of MIPS eligible clinicians submitted by the QCDR may result in notations of low data quality and would place the QCDR on probation.

While STS believes it is critical that CMS use accurate data to perform its analysis, STS opposes this proposal. We do not believe QCDRs should be held responsible for TIN/NPI mismatches, as QCDRs rely on the eligible clinicians to provide accurate TIN/NPI information. Rather, we request that CMS allow QCDRs to run tests similar to SEVT testing, ideally in the middle of the performance period, to allow QCDRs to determine whether TIN/NPI inaccuracies exist. **Furthermore, until we have all gained experience with MIPS, we do not believe QCDRs should be placed on probation should the QCDR submit data with inaccuracies**. This should be consistent across document and measurement criteria. There should be no adverse consequences until accuracy of methods has been verified.

CMS acceptance of QCDR Data (including risk adjusted data)

CMS proposes to require QCDRs submitting MIPS quality measures that are risk-adjusted (and have the risk-adjusted variables and methodology listed in the measure specifications) to submit the risk-adjusted measure results to CMS when submitting the data for these measures.

STS supports this proposal. **Furthermore, while we agree with this policy, we believe it is critical that CMS work with registries to ensure that CMS can accept formats that allow each registry to demonstrate the unique features of its data, especially embedded risk**

adjustment. CMS must recognize that risk adjustment, like financial data reporting, is subject to data run-out. A patient's longitudinal follow-up may extend into the next reporting period and risk adjusted measures will eventually be accurate over an annual basis.

The STS National Database, which has more than 6.8 million patient records, has long used risk adjustment to provide more accurate patient clinical outcomes. The STS Risk Calculator (available to the public here: http://www.sts.org/quality-research-patient-safety/quality/risk-calculator-and-models/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 the 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.

There is now an increasing recognition nationally that performance measurement must be more comprehensive than just single procedures and outcomes. Because of such considerations, many organizations have recommended the use of multiple measures of quality for specific conditions and procedures, sometimes combining them into one number called a composite score. The composite score is a single number or rating that summarizes all available information about the quality of care delivered by an individual provider. It is this principle that led The Society of Thoracic Surgeons to develop what is known as the STS Coronary Artery Bypass Graft (CABG) composite score and rating, now one of the most sophisticated and widely regarded overall measures of quality in health care. Subsequently the STS Aortic Valve Replacement (AVR) composite score and most recently the STS AVR+CABG composite score were developed due to the success of its CABG predecessor, and further composite measures for other procedures are currently being developed. We offer our assistance to CMS with respect to developing policies related to risk adjustment in the future.

With respect to data on non-MIPS QCDR measures, CMS proposes at §414.1400(f) the QCDR must provide the following information:

- *Provide descriptions and narrative specifications for each measure activity or objective for which it will submit to CMS by no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and ACI) data. In future years, starting with the 2018 performance period, those specifications must be provided to CMS by no later than November 1 prior to the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and ACI) data.*

  For the reasons above regarding the need for more time to submit self-nomination statements, STS opposes the proposed January 15 deadline for QCDRs to provide descriptions and narrative specifications for each measure activity, or objective for which it will submit to CMS. **We believe QCDRs should be given until March 31 of the applicable performance period (that is March 31, 2017 for the 2019 MIPS payment adjustment) to submit this information**. Measure specifications in the STS database are refreshed in accordance with NQF standards and the adjustments may not occur conveniently within these calendar corridors as described.

- *For non-MIPS quality measures, the quality measure specifications must include: name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. The narrative specifications provided must be similar to the narrative specifications CMS provides in its measures list. CMS will consider all non-MIPS measures submitted by the QCDR but the measures must address a gap in care and outcome or other high priority measures are preferred. Documentation or "check box" measures are discouraged. Measures that have very high performance rates already or address extremely rare gaps in care (thereby allowing for little or no quality distinction between MIPS eligible clinicians) are also unlikely to be approved for inclusion.*

  STS supports this proposal.

Technical Assistance

Section 1848(q)(11) of the Act, as added by section 101(c) of the MACRA, provides for technical assistance to MIPS eligible clinicians in small practices, rural areas, and practices located in geographic health professional shortage areas (HPSAs). In general, the section requires the Secretary to enter into contracts or agreements with appropriate entities (such as quality improvement organizations, regional extension centers (as described in section 3012(c) of the Public Health Service (PHS) Act), or regional health collaboratives) (such as those identified in section 1115A of the Act) to offer guidance and assistance to MIPS eligible clinicians in practices of 15 or fewer eligible clinicians. Details regarding the technical assistance program are outside the scope of this proposed rule, and will be addressed in separate guidance.

While there are no current proposals related to technical assistance, we stress the importance of providing substantial technical assistance to MIPS eligible clinicians and groups on the implementation of MACRA, particularly to small practices. As CMS notes in Table 64 of the proposed rule, the 2019 MIPS payment adjustments are expected to more negatively affect small practices and solo practitioners compared to larger group practices. We believe there is a knowledge gap for small practices and solo practitioners who do not have the time or additional staff to keep up with ever changing and increasingly complex requirements. In order for these clinicians to be successful, it is critical that technical assistance is offered to these clinicians as soon as possible.

Performance Measurement Categories
Quality

As a leader in quality measurement and reporting, STS would like to emphasize some additional principles related to quality measurement, particularly as it relates to procedure-based specialty medicine. It is important that CMS recognize that quality improvement in specialty medicine can be very different from quality improvement in primary care. Because specialists' patient interactions may be more specific to a procedure, specialists may have less opportunity to implement cross-cutting quality measures. However, procedure-based medicine is perfectly

suited for patient outcomes quality measurement. STS has sponsored more National Quality Forum-endorsed quality measures (34) than any other professional organization, and these include risk-adjusted morbidity and mortality measures that have already driven change and improvements in care for Medicare beneficiaries.

That said, it has also proven very difficult for procedure-based medicine to measure patient experience as a quality measure. Most of what we collect in the STS National Database is procedure-based for a single episode of care. Hospitals and providers don't have the resources to contact patients after the global payment period is over to assess patient satisfaction and quality of life. We look to CMS to help procedure-based specialists and hospitals to implement better patient satisfaction measures. This may require additional resources and incentives for hospitals to implement new patient experience measurement protocols.

Reporting Thresholds/Reporting Option for QCDR

Generally, CMS proposes that an eligible clinician or group would report at least six measures including one cross-cutting measure and at least one outcome measure, or, if an outcome measure is not available, report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures). If less than six measures apply, then report on each measure that is applicable. If an eligible clinician or group chooses to submit quality measures data via a qualified registry, EHR, or QCDR, CMS proposes that the eligible clinician or group would be required to report quality measures data on at least 90% of all patients.

If reporting via a QCDR, STS supports CMS' proposal that an eligible clinician or group would report at least six measures including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures).

While we recognize the desire to move toward the goal of collecting quality data on every patient and hope that one day this becomes a fundamental part of practice, **STS opposes the CMS proposal to dramatically increase the proposed reporting thresholds for QCDRs, especially during this transition period. In order to facilitate development of QCDRs in other specialties and primary care, we request that CMS reduce the data completeness threshold to 50%, which is currently the minimum required threshold for data completeness in PQRS, at least in the initial years of MIPS and consider gradually increasing it in the future**. This is particularly important as we transition to MIPS. Although STS can accomplish the proposed threshold, our concern is that other professional organizations developing or participating in QCDRs will fail this requirement reverting to a system of manual reporting with a much higher infrastructure burden, more variability and a less dependable national picture of provider performance.

Group Reporting

CMS does not propose to require groups to register to have their performance assessed as a group except for groups submitting data on performance measures via participation in the CMS Web Interface or groups electing to report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey for the quality performance category.

While STS supports this proposal, we note our continued frustration with the requirements surrounding the option to participate as a group. Specifically, it is difficult to assess performance at the TIN when eligible clinicians change jobs and therefore can change TINs during the year. As an eligible clinician's NPI does not change, the NPI appears to be a more stable unit of measurement. We urge CMS to find ways to rectify ongoing issues surrounding the changing of TINs. As written, it will be very difficult for CMS to administer relevant payment adjustments and for providers to reconcile them within multiple TIN.

In addition, STS recommends that individual eligible clinicians within a TIN be allowed to opt out of multi-specialty group reporting. While we see the advantages of participating as a group, we are concerned that the multi-specialty group practice option may have the consequence of drowning out specialty specific measures in multi-specialty practices. Particularly as we move towards being measured on performance, we believe eligible clinicians should have a choice in determining how to be assessed, even within the group option.

Physician Individual Reporting Opt-In

STS appreciates that CMS proposes to preserve the individual and group reporting mechanisms and to expand reporting options available to specialty group practices by giving them the choice to report as a group across all four MIPS performance categories. The group practice reporting option is important to many clinicians since it provides an opportunity to reduce the participation burden that could be experienced by larger groups that would otherwise have to report data for each individual.

At the same time, we note that the group practice reporting option does not always incentivize true team-based approaches to care that are foundational to raising the bar on quality. Under PQRS, individual physicians often have little to no control over their groups' measure selections, reporting mechanisms, and overall participation decisions. Often, individual specialists within a larger multispecialty group are not even aware that their group is reporting measures on their behalves. While this might allow some individual members of the group to avoid penalties without the burden of reporting on any measures, this concept seems to contradict CMS' goal of incentivizing meaningful participation across specialties and does little to promote care-coordination.

Since MIPS represents an unprecedented shift from pay-for-reporting to pay-for-performance and expanded accountability both in terms of payment adjustments and public reporting, it is critical to ensure that individual clinicians have direct control over participation decisions. We reiterate our recommendation that CMS adopt a policy that would give individuals the option to be evaluated as an individual even if their group elects to use group reporting. This would provide individual clinicians with the flexibility to demonstrate their unique contributions to

quality improvement in situations where they might otherwise be held accountable for cases attributed to the group for which they have no direct control over.

Although CMS does not propose any specific policies related to "virtual groups" for the first year of MIPS, we see great potential value in this mechanism since it would give individuals the flexibility to determine if they want to be evaluated as part of a unique group of clinicians that might not necessarily align with their billing TIN, and to determine which other individuals best represent their "care team."

In regards to group reporting across all MIPS performance categories (not just quality), we urge CMS to provide more specific details on how it plans to evaluate group performance and determine payment adjustments based on group performance under each of the four MIPS performance categories. These details are critical since MIPS represents the first time group practices would be allowed to demonstrate meaningful use of EHRs and report on CPIAs as a group. Will CMS evaluate each individual within the group and combine those scores into a composite group score or will it look at group performance, as a whole, as it currently does under PQRS (e.g., in accordance with the proposed quality reporting threshold, did the group, as a whole, report on six quality measures for 90% *of the group's* applicable patients)? While it might be feasible to evaluate group level performance for quality and resource use and then apply that score to everyone in the TIN regardless of whether all individuals in the group contributed to the score, that strategy does not translate as easily to the new ACI and CPIA categories.

Application of Additional System Measures

CMS seeks comment as to whether it should attribute a facility's performance to a clinician for purposes of the quality and resource use performance categories and under what conditions such attribution would be appropriate and representative of the clinician's performance. CMS also requests possible criteria for attributing a facility's performance to a clinician for purposes of the quality and resource use performance categories; specific measures and settings for which CMS can use the facility's quality and resource use data as a proxy for the MIPS eligible clinician's quality and resource use performance categories; and whether attribution should be automatic or have a MIPS eligible clinician or group elect attribution of a certain facility's measures through a registration process.

For many specialties, and ours in particular, procedures can only be done in the inpatient setting (e.g., CABG, valve replacement, lobectomies) and quality and resource use are inextricably linked. An eligible provider or his/her group can perform these procedures in multiple institutions under the same TIN. Facility infrastructure, resource use and costs vary from facility to facility. Using a facility-specific DRG weighting would be an appropriate modification to an eligible provider's resource use data. Some facilities (e.g., academic centers) may accept much higher risk patients and also have very different cost profiles. STS would support using a facility's resource use/costs as a proxy in combination with appropriate grouper technology to avoid attribution of complicated patient's resource use to a specialist not involved in the total episode of care of the patient. An appropriate

QCDR should always be used for monitoring of quality as it will apply specifically to the care delivered

STS supports the use of additional system measures so long as clinicians have the freedom to elect to be held accountable under these other types of measures and to select the facility(ies) that it wants to be attributed to. Given the implications for payment and public reporting, CMS must not apply these measures automatically and without the consent of the clinician.

Benchmarking

CMS proposes to base the benchmarks on performance in the baseline period (two years prior to the performance period for the MIPS payment year) when possible, and to publish the numerical benchmarks when possible, prior to the start of the performance period. If CMS does not have comparable data from the baseline period, CMS proposes to use information from the performance period to establish benchmarks. When developing the benchmarks, CMS would identify the clusters and state the points that would be assigned when the measure performance rate is in a cluster. CMS proposes to assign 1-10 points to each measure based on how a MIPS eligible clinician's performance compares to benchmarks.

STS opposes basing benchmarks on a baseline period occurring two years prior to the performance period for the MIPS payment year. We do not believe that CMS should apply benchmarks that determine an eligible clinician's or group's score in the quality performance category based on data from a timeframe that occurs approximately four years prior to the MIPS payment adjustment year. We note that quality programs and measures may evolve significantly within four years. As such, using benchmarks based on an outdated baseline period may not truly represent the design and makeup of the measure that is being reported. In addition, to promote overall transparency as to how eligible clinicians will be scored on performance, we request to see and have the opportunity to provide input on the benchmarks CMS establishes for the initial year of MIPS.

To ensure that MIPS eligible clinicians are measured reliably, CMS proposes to use a 20 case minimum requirement for all quality measures. In addition, CMS proposes that MIPS eligible clinicians who report measures with a performance rate of 0 percent would not be included in the benchmarks.

STS supports this proposal.

CMS proposes to create separate benchmarks for submission mechanisms that do not have comparable measure specifications. CMS proposes to develop separate benchmarks for EHR submission options, claims submission options, Qualified Clinical Data Registries (QCDRs) and qualified registries submission options.

STS supports this proposal.

CMS considered not scoring measures that either are new to the MIPS program or do not have a historical benchmark based on performance in the baseline period.

STS supports this proposal.

CMS proposes to limit the maximum number of points a topped out measure can achieve based on how the scores are clustered. CMS proposes to identify clusters within topped out measures and would assign all MIPS eligible clinicians within the cluster the same value, which would be the number of points available at the midpoint of the cluster.

STS opposes this proposal and believes that all measures within the quality performance category should receive the same maximum number of points. We believe that CMS should allow eligible clinicians to gain experience with MIPS before establishing a proposal whereby some measures would be weighted more heavily than others.

Public Reporting/Physician Compare

In general, STS opposes the public display of MIPS information on Physician Compare until eligible clinicians and groups have had experience with participating in the new Quality Payment Program. In addition, we request that CMS preserve the policy of giving QCDRs the option to post data that would be available on Physician Compare on their respective websites in a manner and format that the QCDR believes is most appropriate (e.g., reporting data at a more aggregate or group level).

CMS proposes that the composite score for each MIPS eligible clinician, performance of each MIPS eligible clinician for each performance category, and periodically post aggregate information on MIPS would be added to Physician Compare for each MIPS eligible clinician or group, either on the profile pages or in the downloadable database, as technically feasible.

STS opposes this proposal. We believe that the composite score for each MIPS eligible clinician as well performance of each MIPS eligible clinician for each performance category should not be posted on Physician Compare until eligible clinicians and groups have had the opportunity to participate in the QPP for at least two years. We believe it will take at least two years for eligible clinicians and groups to gain familiarity with the program and believe data in the QPP's initial years may not reflect accurate performance.

CMS proposes that all measures in the quality performance category that meet the public reporting standards would be included in the downloadable database, as technically feasible. In addition, a subset of these measures would be publicly reported on the website's profile pages, as technically feasible.

STS requests clarification on how non-MIPS measures submitted by QCDRs would be posted on Physician Compare. Specifically, would CMS post all non-MIPS measures on the Physician Compare website or allow QCDRs to post this information on the QCDR website?

With respect to the resource use performance category, CMS proposes to include a sub-set of resource use measures, that meet the aforementioned public reporting standards, on Physician Compare, either on profile pages or in the downloadable database, if technically feasible.

Due to our concerns regarding the proposed measures in the resource use performance category, STS opposes display of any information regarding the resource use performance category on Physician Compare. Further we do not believe that any MIPS-related data should be reported publicly for 1-2 years after implementation - until providers and systems have become familiar enough with the system. This will also ensure that consumers will have access to relevant information rather than variations that reflect administrative startup difficulties.

Resource Use
Weight

CMS proposes that the resource use performance category would make up 10 percent of the CPS for the first MIPS payment year (CY 2019) and 15 percent of the CPS for the second MIPS payment year (CY 2020).

Based on our members' practice, it is unclear whether the resource use performance category would apply to STS members. We note that CMS is proposing to use exiting VM measures for the resource use performance category of MIPS. We are concerned with the methodology that would continue to be used to calculate cost composite scores. Specifically, we do not believe the current methodology is reliable and valid for all practice sizes. Until CMS develops an alternative to the current measures used in the VM, STS requests that CMS use its authority under section 1848(q)(5)(F) of the Act to reweight the resource use performance category to zero for future MIPS payment adjustments. Until changes are made to these measures, we do not believe it's appropriate to assess eligible clinicians in this category. Therefore, we also do not believe CMS should increase the weight of this performance category for the 2020 MIPS payment adjustment. Instead, we recommend that CMS redistribute the MIPS composite score to further emphasize the quality and CPIA components of the MIPS score.

If CMS ultimately finalizes its decision to maintain these measures, we at least urge the agency to make the following changes**. CMS proposes to establish a 20 case minimum for each resource use measure, including the Medicare Spending Per Beneficiary (MSPB) measure which currently has an established case minimum of 125**. STS opposes CMS' proposal to use a 20 case minimum rather than the 125 case minimum currently established under the VM. We believe CMS should retain the 125 case minimum. In previous rulemaking, CMS stated that it conducted a study and determined the 125 case minimum more appropriate for the MSPB measure than a 20 case minimum, particularly as smaller groups and solo practitioners were added to the VM. In the 2016 PFS final rule, CMS stated that,

> It would not be appropriate to include this measure in the cost composite with a 20-episode minimum at a sample size that does not produce reliable results even for those groups that performed well. Rather, we believe that it is more important to ensure that only reliable measures are included in the VM, and we want to

> avoid a situation in which groups or solo practitioners who may have performed poorly on the measure using a 20-episode minimum may receive a downward adjustment to payments under the VM as a result of a measure that was not reliable. (80 FR 71296).

In addition, we note that STS supports the use of risk adjustment and the use of better attribution methodologies, particularly within episode groups. Most notably, we are concerned about CMS' ability to capture the changing roles of the provider throughout the episode of care. In addition, we believe CMS must continue to work towards the development of more accurate patient relationship codes to better define patient visits. We believe the use of episode groups could be beneficial to providing more accurate data as the episode groups are further refined and developed.

For the resource use performance category, CMS proposes to maintain some of the cost measures used under the Value Modifier (VM), including the Medicare Spending per Beneficiary (MSPB) measure without applying the specialty adjustment and the total Per Capita Cost measure. In addition, CMS is proposing to use existing condition and episode-based measures selected from 41 potential episodes.

STS believes that it is important that comparisons account for case-mix differences between practitioners' patient populations and the national average. Further, it is important to recognize and account for the resource differences for physicians who treat more complex patient populations. CMS proposes to remove the specialty adjustment from the MSPB measure because it appears to be unclear whether the current adjustment for physician specialty improves the accounting for case-mix differences for acute care patients. Until further information is available supporting that the specialty adjustment factor does not improve the accounting for case-mix differences for acute care patients, **STS encourages CMS to continue to apply the specialty adjustment to the MSPB measure**.

STS agrees that properly designed, measures tied to episodes of care could increase the relevance, reliability and applicability of resource measures and make physician feedback reports more actionable. CMS is initially proposing inclusion of up to 41 condition and episode-based measures and continued development of additional condition and episode-based measures. Although CMS indicates that the proposed episodes and logic have undergone detailed and rigorous evaluation by an independent evaluation contractor and that CMS also reviewed for clinical validity, STS is concerned that that the episodes did not have enough clinical stakeholder input and do not accurately represent the resources involved for an episode of care. CMS also indicates that they will continue to engage stakeholders to refine and improve the episodes moving forward. **STS strongly encourages CMS to create a process that provides an opportunity for thorough input from practicing physicians that allows for transparency and stakeholder involvement in the refinement of the existing measures and development of new measures and the accompanying methodological decisions.** Posting information on the CMS website about care episodes generated by a contractor and reviewed by a handful of "experts" is insufficient. We request that CMS hold a listening session to generate feedback on these episode-based measures.

CMS requests comment on which measures should be included in the final rule. In Table 4: Proposed Clinical Condition and Treatment Episode-based Measures Developed Under Section 1848(n)(9)(A) of the Act (Method A) under Cardiovascular.

STS supports the use of the measures for Aortic/Mitral Valve Surgery and Coronary Artery Bypass Graft (CABG), which were utilized in the 2014 QRUR. However, we are extremely concerned that these measures do not accurately represent the resources involved in those episodes of care and we are unsure of what the impact of being measured using episode groups will have on our members. **Therefore, we request that CMS pilot the use of episode groups for the resource use for performance category for the first year of MIPS. We also request that CMS provide information on performance on episode groups in the feedback reports but not use these data to determine a MIPS eligible clinician or group's score for the resource use performance category and overall composite performance score.**

STS also has concerns surrounding correct attribution. The current VM measures are irrelevant for many physicians—either because no patients are attributed to them or because the physicians have little to no opportunity to influence the costs that are attributed to them. Additionally, for inpatient episodes of care the current VM uses a plurality approach which will cause inappropriate allocation of resources for inpatient resource utilization as many physicians of different specialties care for these patients and utilize resources in many different but important ways (testing, procedures, imaging and per diem charges using E&M codes). **STS encourages CMS develop a process that allows MIPS eligible clinicians a mechanism to review, question and remove inappropriately attributed episodes. Additionally, CMS must devote significant data analysis and resources to this effort in order to replace, not expand, the current VM cost measures.**

CMS is charged with developing patient and relationship categories to further assist with attribution. STS encourages CMS to create codes that have the ability to capture the changing roles of a provider throughout an episode of care. In addition, CMS has acknowledged public support for the development of new measures based on clinical practice guidelines (CPGs) and/or appropriate use criteria (AUC) and for the related "Choosing Wisely" campaign. CMS noted that in future years, specialties might decide to use these in the creation of resource use measures. A growing number of specialties have developed and continue to expand and refine evidence based clinical practice guidelines (CPGs) and appropriate use criteria (AUC). Incorporation of such CPG and AUC into clinical registries should be encouraged to facilitate the creation of resource use measures. **We encourage CMS to work with all affected specialties to integrate such measures into the resource use category of MIPS.** STS feels that CMS should develop a process that allows medical specialty associations to determine cost saving measures, which are appropriate for their members. Resource categories should be risk-adjusted and should take into account the geographic location of the hospital, the type of hospital (teaching vs. nonteaching) and the physician specialty.

Advancing Care Information

CMS largely proposes to incorporate Stage 3 (or, alternatively, modified Stage 2) requirements from the EHR Incentive Program in this performance category. Many eligible clinicians do not have the ability to meet these requirements, so we do not believe it is appropriate to transfer the requirements established in the EHR Incentive Program to MIPS. The proposal for scoring points under the ACI performance category is higher than the proposed requirement for eligible clinicians in advanced APMs to use CHERT.

With respect to advanced APMs, CMS proposes that an Advanced APM must require at least 50 percent of eligible clinicians who are enrolled in Medicare to use the CEHRT functions (as outlined in the proposed CEHRT definition) "to document and communicate clinical care with patients and other health care professionals." As proposed, a QP in an advanced APM would not be required to meet the objectives and measures in the EHR Incentive Program. We do not believe it is fair to require eligible clinicians in MIPS to be held to a higher standard of needing to report on objectives and measures. **Therefore, we believe that eligible clinicians should receive full credit under the ACI performance category by fulfilling the same requirement that would be required for QPs in Advanced APMs: at least 50 percent of eligible clinicians who are enrolled in Medicare to use the CEHRT functions (as outlined in the proposed CEHRT definition) "to document and communicate clinical care with patients and other health care professionals."**

Clinical Practice Improvement Activities

As part of the CPIA Patient Safety and Practice Assessment Subcategory of activities, CMS includes:

> *Participation in Maintenance of Certification Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.*

In addition, CMS proposes that this activity would be "medium priority," and thus worth only 10 of the 60 CPIA points needed to achieve the highest potential score.

STS believes that, at the very least, CMS should re-designate this activity as a high priority. While we believe that participation in MOC Part IV should enable a physician to receive an even higher CPIA score, CMS should acknowledge the effort and resources that are dedicated to an activity that's importance and value is recognized by every board and medical specialty. These activities, which are required by all member boards in the American Board of Medical Specialties (ABMS) and which require physician engagement in practice performance improvement efforts, are quintessential practice improvement activities and believe that should be reflected in the ability of participation in MOC Part IV to contribute to an Eligible Clinicians CPIA score. The types of activities which are appropriate for each specialty are determined by that specialty's Board under the oversight and approval of ABMS, and we firmly believe CMS should acknowledge and defer to that expertise in its weighting of this activity.

STS also recommends that, to ensure that participation in MOC Part IV is accurately represented in the CPIA scoring proposals, CMS should utilize its approach of incorporating the various aspects of QCDR participation in the list of CPIAs by separately listing the MOC Part IV activities as either medium or high as well. This will allow Eligible Clinicians who demonstrate participation in all aspects of MOC are able to attest to each of those different MOC Part IV related activities in order to achieve a higher cumulative CPIA score beyond the 10 points CMS is now proposing to dedicate to engaging in MOC Part IV. This would not only be appropriate because of the intensity of MOC Part IV, but also because of its emphasis on clinical data registries. For instance, in thoracic surgery, diplomates must provide the name of the clinical outcome database that they use to improve their practice. Starting in 2012, the Board began requiring all Active Diplomates to participate in a national, regional or state-mandated outcomes database approved by the Board. We are proud that STS database meets the American Board of Thoracic Surgery Maintenance of Certification Part IV-Evaluation of Performance in Practice.

We feel that these kinds of activities are exactly what was contemplated by Congress when it created CPIAs, and strongly request that the activities surrounding MOC Part IV should be given more value in the CPIA scoring proposals, similar to CMS' CPIA approach with QCDRs.

Alternative Payment Models

Advanced Alternative Payment Models

We are very disappointed with CMS's decision not to adopt new policies or procedures to implement Section 105(b) of MACRA (Pub. L. 114-10). Section 105(b) requires CMS to provide QCDRs with access to Medicare data for purposes of linking such data with clinical outcomes data and performing scientifically valid analysis or research to support quality improvement or patient safety. CMS decided not to issue a rulemaking on this section of the law based on its assertion that QCDRs can currently request Medicare claims data through the ResDAC data request process. Such a position also runs counter to the intent of the MACRA legislation in that CMS has a mandate to help providers participate in the process of APM development. It is impossible for providers to know how design an APM and accept financial risk without having a clear picture of how patients access the health care system and what those associated costs are.

The CMS position on Section 105(b) also mistakenly assumes Congress was not aware that QCDRs could apply for access to Medicare claims data through the ResDAC process and blindly directed CMS to provide QCDRs with access to data that was already available to them. CMS also ignores the fact that Section 105(b) is intended to provide QCDRs with access to Medicare data for quality improvement purposes, not just research, and that the broad and continuous access needed for quality improvement purposes is fundamentally different than the access to Medicare data for research purposes provided by ResDAC. Providing QCDRs with regular and timely access to Medicare claims data is critical to the future of Medicare payment policy, which is now inextricably linked to quality improvement and resource use. It will also dramatically increase the power of clinical outcomes data collected by QCDRs and therefore yield immeasurable benefits for patient health and safety. Lastly, CMS should match Medicare claims

data with Social Security Death Masterfile (SSDMF) death data before providing it to QCDRs to greatly enhance the accuracy and robustness the Medicare claims data.

The Decision Not to Issue a Proposed Rule is Contrary to Congressional Intent

CMS is required to interpret a governing statute so as to give meaning and effect to the plain language of the law. It may not construe the statute in a manner that renders one or more provisions superfluous. CMS's decision not to issue a proposed rule implementing Section 105(b) violates these black letter principles of statutory construction.

Section 105(b) of MACRA specifically and unequivocally requires CMS to make Medicare claims data available to QCDRs so that they can link such data with the robust clinical information contained in registries like the STS National Database. STS and the Physician Clinical Registry Coalition, a group of more than 20 other physician-led clinical data registries, advocated for the inclusion of Section 105(b) in MACRA because patient outcomes information derived from the seamless combination of these data sources, when linked with Medicare claims data, creates a powerful tool for tracking patient outcomes over an extended period of time. The implications of such longitudinal studies for quality improvement are dramatic. Importantly, having access to Medicare claims data will also facilitate implementation of alternative payment models. By combining the STS National Database and claims information from Medicare and other payors in a new alternative payment model structure, providers will be able to identify high impact areas for improvement based on quality or costs or both.

Congress enacted Section 105(b) with full understanding of the powerful synergies created when clinical outcomes data is married with administrative claims data. It knew full well that Medicare claims data was available to Qualified Entities and others, including QCDRs, through the ResDAC process. Yet, it still directed CMS to provide QCDRs with access to Medicare claims data for the purposes specified in the statute. If Congress were satisfied with fact that QCDRs could request claims data from ResDAC, it would not have included Section 105(b) in MACRA. Thus, CMS's decision not to issue new policies and procedures providing QCDR's with access to Medicare data beyond that currently available from ResDAC violates the clear intent behind Section 105(b) and longstanding rules of statutory construction.

CMS Must Provide QCDRs with Access to Medicare Claims Data for Quality Improvement Purposes, Not Just Research

Section 105(b) requires CMS to provide QCDRs with access to Medicare claims data "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research ***to support quality improvement or patient safety***." (Emphasis added.) Thus, the primary purpose of this section is to promote quality improvement, not research. This point is confirmed by the heading of the section: "Access to Medicare Claims Data by Qualified Clinical Data Registries to Facilitate Quality Improvement." CMS's statement in the Proposed Rule that "The CMS research data disclosure policies already allow qualified clinical data registries to request Medicare data for these purposes, ***as well other types of research***" (emphasis added) demonstrates the agency's misunderstanding of the purpose of

Section 105(b) and the sharp distinction between research and quality improvement activities. This distinction is codified in the regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which clearly distinguish between research and quality improvement activities (a form of "health care operation") for purposes of protecting the privacy of patient identifiable information.

Moreover, Section 105(b) directs CMS to provide Medicare claims data to QCDRs for purposes of ***linking*** that data with clinical outcomes data. That language suggests that QCDRs must have broad and continuous access to large Medicare claims database, such as the 100% Medicare inpatient claims file, in order to conduct the probabilistic matching and linking process. As its name (Research Data Assistance Center) indicates, ResDAC provides Medicare claims data for discrete research projects. It requires applicants to submit proposals for such projects that identify specific cohorts of patients and specific protocols for conducting research studies on such cohorts. It then provides only the Medicare data necessary to perform that project. ResDAC also has a cumbersome application process that (a) does not guarantee access to data by an applicant, and (b) typically takes weeks and sometimes longer from application to approval.

By contrast, QCDRs require, and Congress intended to provide them with, timely and continuous access to large Medicare data sets to carry out the linking process and thereby enhance the power of their clinical outcomes databases to track patients over time, to capture all relevant procedures or surgeries within a particular field or specialty, and to perform ongoing data aggregation services for their participants. Their needs are not limited to discrete research projects.

Congress' intent was that by virtue of meeting the requirements to become a QCDR, these registries would automatically be eligible for access to Medicare data for linking purposes. Requiring them to take their chances in the ResDAC process directly contravenes the purpose of Section 105(b). While there needs to be some mechanism for identifying and evaluating a QCDR's data linking needs, defaulting to the ResDAC research request process is not answer. CMS should be well aware of the fact that ResDAC is not the appropriate mechanism for meeting the objectives of Section 105(b). STS, the American College of Cardiology, and other established clinical data registries have linked their data with Medicare claims data on numerous occasions without going through ResDAC process. Rather, they have worked directly with CMS to obtain data from the 100% Medicare inpatient claims file and other databases not available through ResDAC. Based on these experiences, CMS should know that it needs to establish a separate, more streamlined process that gives QCDRs timely access to broad Medicare data sets for purposes of linking such data with clinical outcomes data to support quality improvement activities.

The Secretary Should Match Medicare Claims Data with SSDMF Data Before Providing It to QCDRS

The Social Security Administration used to have a policy of sharing state-reported death data in the Social Security Death Master File (SSDMF) with third parties, including clinical data registries. This 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 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 U.S.C. § 405(r)(9) to match Medicare claims data with death data contained in the full SSDMF data file (not just the public SSDMF available to entities that meet certification criteria). Because the ultimate purpose for accessing death data was to enhance the accuracy of patient outcomes information, including verification of patient life status and date of death, and not the acquisition of the actual death data set itself, QCDRs would greatly benefit from the Secretary matching Medicare claims data with SSDMF death data to verify patient death status, and sharing the matched data set with QCDRs. This would be a permissible exercise of the Secretary's authority under 42 U.S.C. § 405(r)(9) and provide QCDR's with much more useful data for linking purposes.

Advanced APM Criteria

Use of Certified EHR Technology (CEHRT) *CMS proposes that an Advanced APM must require at least 50 percent of eligible clinicians who are enrolled in Medicare to use the CEHRT functions "to document and communicate clinical care with patients and other health care professionals." This threshold for use of CEHRT would increase to 75 percent beginning with the second QP Performance Period.*

STS is supportive of this proposal. We firmly believe that the use of CEHRT in APMs should follow a patient-centered outcomes approach rather than one that is tied to process measures and "counting clicks" to meet thresholds. By defining the use of CEHRT as "to document and communicate clinical care with patients and other health care professionals," CMS is allowing Advanced APMs to design CEHRT use in the most appropriately patient-centric for that model without falling into the pitfalls that we have seen with the measures and objectives that have provided little value to the EHR Incentive Program. As many proposals for new APMs will be developed by stakeholders and not CMS, we appreciate that the traditional concepts utilized in the EHR Incentive Program (and are unfortunately, in many ways, carried into the MIPS ACI performance category) are not incorporated into the criteria here which could have hindered the development of specialized health IT modules that support the goals of APMs.

We also continue to believe that interoperability among various EHR modules and between EHRs and other data sources such as clinical data registries is absolutely essential to the successful implementation of APMs. However, because this criterion is anchored to the use of CEHRT, we believe that interoperability issues can be addressed at the EHR certification level and need not be added as a separate hurdle that only Advanced APMs must cross.

MIPS-Comparable Quality Measures*. CMS proposes that the quality measures on which the Advanced APM bases payment must include at least one (1) of the following types of measures (provided that the measures have an evidence-based focus and are reliable and valid)[1]:*

- *Any of the quality measures included on the proposed annual list of MIPS quality measures;*
- *Quality measures that are endorsed by a consensus-based entity;*
- *Quality measures developed under section 1848(s) of the Act (i.e. quality measures as part of the Secretary's Quality Measure Development Plan)*
- *Quality measures submitted in response to the MIPS Call for Quality Measures; or*
- *Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.*

STS is supportive of CMS proposals related to the required use of MIPS-comparable quality measures. We believe the proposal provides structure to ensure that the legislative provision is implemented but the flexibility to allow models to focus on the quality measures most appropriate to that APM. STS maintains the most NQF-endorsed quality measures of any other entity, and **we are, therefore, very encouraged that CMS states in the proposed rule that measures that are endorsed by the NQF would meet these criteria**. We are proud of our ability to develop and implement meaningful quality measures. Our surgeons utilize the STS National Database to help them improve their care and reach new quality benchmarks. We believe that it is absolutely essential to the success of APMs that the provider comprehends the measurement process in order to understand how they can improve.

Financial Risk*. CMS proposes that in order to qualify as an APM that the APM Entity be required to take downside risk. In addition, CMS proposes to define whether that financial risk is "in excess of a nominal amount" by measuring the Total Risk, Marginal Risk, and Minimum Loss right of the APM design. CMS also proposes to assess these financial risk characteristics by reviewing the design of the model rather than requiring that each individual participant incur risk for potential losses.*

STS is supportive of this proposal as we believe it allows APMs and APM Entities to structure their risk arrangements in the manner most appropriate for a given design and in a way that can encourage additional participation in the model.

As part its proposals related to financial risk for Advanced APMs, CMS does not allow for using a measurement of the time and money commitments required in implementation of an APM. However, CMS requests comments on how it could potentially create an objective and meaningful financial risk criterion that would define financial risk for monetary losses based on performance under the APM differently.

[1] CMS also proposes that an Advanced APM must include at least one (1) outcome measure if an appropriate measure is available on the MIPS list of specific measures for that specific QP Performance Period (at the time when the APM is first established).

STS continues to believe that CMS should consider the investment in model development and implementation into the risk equation. For example, APMs that rely on clinical data registry participation should take into account the cost of participating in and maintaining such registry. Start-up costs such as data analysis, establishing procedures for coordinating care and sharing information, and additional costs for new employees such as data managers should also be taken into account. Particularly in physician-focused payment models (PFPMs), the practice may bear these costs with the goal of offsetting them through savings on other services, but if the savings are not achieved elsewhere, the practice will incur additional losses. These potential losses should be a part of assessing whether an APM has met the financial risk criteria.

Qualifying Advanced APM Participation (QP) Determinations

QP Level of Assessment. *Once participation in an Advanced APM has been verified CMS proposes to make determinations of whether the participating Eligible Clinicians meet the required QP thresholds to be eligible for the APM Incentive Payment collectively among all the Eligible Clinicians on the APM Entity's participation list.*

STS is extremely supportive of the proposal to make QP threshold determinations collectively among an Advanced APM Entity's participants rather than requiring each individual participating Eligible Clinician to cross the threshold. As we have stated many times, we believe that one of the main Congressional and stakeholder priorities in supporting the passage of MACRA was to create incentives for physicians to participate in alternative methods of paying for services delivered. We have held concerns that the QP threshold could be very difficult for particular individual physicians or specialties to meet. By proposing to assess the QP thresholds collectively among all Eligible Clinician participants in an Advanced APM Entity, we believe that CMS is creating more opportunity to move more physicians into APMs by ensuring that the APM Entities are meeting the legislatively mandated thresholds while providing the APM Entity to involve the optimal mix of physicians and/or specialties for that model and removing a disincentive to include physicians who might otherwise not be able to individually meet the QP thresholds.

QP Determination Patient Count Methodology. *Once participation in an Advanced APM has been verified, CMS proposes to us both the payment amount and patient count methodologies to determine with the QP thresholds have been met. CMS also proposes that it will assess the APM Entities using both methods and use the QP threshold method that is more favorable to the Advanced APM Entity group of eligible clinicians.*

STS supports the CMS proposal to exercise the authority granted in MACRA to include the patient count methodology for QP determinations as well as CMS' proposal to grant QP status on the most favorable of the two methodologies. Not only does this provide more opportunity for Eligible Clinicians to qualify for the incentive payment, but it also accounts for that fact that in some model designs the most appropriate unit of assessment will be the number of patients treated, while in other model designs payments will provide the better indicator of participation levels. We believe that this is a step in the direction of creating the flexibility

needed in the program to truly incentivize moving into payment arrangements involving performance-based risk.

All-Payer Combination Option. *CMS proposes that APM Entities and/or Eligible Clinicians must submit certain information for CMS to assess whether other payer arrangements meet the Other Payer Advanced APM criteria and to calculate Threshold Scores a QP determination under the All-Payer Combination Option. (For CMS to make QP determinations at the individual Eligible Clinician level in the specified exception cases, either the Advanced APM Entity or the eligible clinician may submit this information with respect to the individual eligible clinician). If CMS does not receive sufficient information to complete its evaluation of the other payer arrangement and perform the QP threshold calculation, CMS states that it would not evaluate the eligible clinicians under the All-Payer Combination Option. CMS states that submissions must include "specific payment and patient numbers for each payer from whom the Eligible Clinician has received payments during the QP Performance Period," in order to calculate the Advanced APM Entity eligible clinician group's (or the individual eligible clinician's Threshold Score in the exceptions case).*

CMS proposes to ask each payer to attest to the accuracy of all submitted information including the reported payment and patient data. Contracts may be subject to audit by CMS. CMS proposes that if a payer does not attest to the accuracy of the reported payment and patient data, these data will not be assessed under the All-Payer Combination Option. Because this requirement leaves eligible clinicians dependent on a payer, CMS seeks comment on alternatives to requiring payer attestation, such as addressing the scope and intensity of audits to verify the submitted data.

STS continues to be concerned that Eligible Clinicians could be reluctant to share their non-Medicare payment information with CMS (and what will be done with that data outside of the QP determination process). **STS recommends that CMS offer the option for physicians to attest to how much non-Medicare payment they receive instead of providing actual data**. We believe that this is appropriate given CMS' history of allowing attestation in the beginning stages of programs, such as the EHR Meaningful Use Incentive Program. We also believe that in order to encourage participation in APMs the process for submitting this information should not add administrative burden to APM participant Eligible Clinicians. After the initial implementation/attestation phase, the APM may identify ways to utilize existing clinical data registries or other sources in reporting these data.

Advanced APM Incentive Payments

CMS proposes that for eligible clinicians that are QPs, CMS would make the APM Incentive Payment to the TIN that is affiliated with the Advanced APM Entity through which the eligible clinician met the threshold during the QP performance period.

STS supports this proposal as it allows for maximum flexibility in the development of APMs, their various organizational structures, and the ways in which revenues might flow through Advanced APM Entities. CMS should not require all APM Entities to be organized

the same way. In some cases, an APM could involve a medical practice, and in others it may include multiple practices, a hospital or home health agency, and other facilities or providers. Different APM designs will require different types of APM Entities. However, while we understand the proposal to administer the incentive payment to the TIN of the APM Entity, we continue to believe that safeguards must be in place that ensure that the physicians participating in the APM are able to influence the governance policies of the APM entity. Therefore, **we continue to request that CMS should require APM Entities to provide for meaningful participation in governance by physicians regardless of whether APM Entity is physician-owned**.

CMS also proposes to send notifications to both Advanced APM Entities as well as their individual participating QPs of their APM Incentive Payment amount as soon as CMS has calculated the amount of the APM Incentive.

STS supports this proposal but also requests that CMS direct the APM Entity to take responsibility for providing information to the participating Eligible Clinicians on the revenue shares attributable to that Eligible Clinician based on the arrangement between the APM Entity and the Eligible Clinician. While we continue to believe that CMS should provide the APM Entities with the flexibility to design their risk and revenue sharing arrangements, we also remind CMS that the APM Incentive Payment was designed to incentivize participation in APMs. The methods that an APM entity uses to distribute APM revenues to the physicians and other health professionals participating in the APM should foster collaboration among the team. If CMS were to establish stringent requirements, this is likely to inhibit that goal. We believe that the distribution of payments to providers should be the result of decisions made at the APM Entity level. However, we also believe that APM Entities should function in an environment of transparency. By asking the APM Entities to provide its participating Eligible Clinicians with information regarding how the APM Entity intends to invest the APM Incentive Payment (without necessarily requiring its distribution to participants), we believe that CMS can create the needed flexibility in the program while ensuring that Eligible Clinicians have the information needed to determine whether these payments are truly an incentive to participate in these types of models.

CMS also offers a series of proposals related to isolating the claims on which the payment incentive should be based. For instance, CMS proposes to exclude the MIPS, VM, MU and PQRS payment adjustments when calculating the estimated aggregate payment amount for covered professional services upon which to base the APM Incentive Payment amount. CMS also proposes to exclude financial risk payments such as shared savings payments or net reconciliation payments, when calculating the estimated aggregate payment amount under the APM Incentive payment.

STS believes that these types of proposals are appropriate in that the APM incentive payment should be based on the value of services that the physician actually provided, not on the payment adjustments (e.g. bonuses or penalties) that affect reimbursement due to other programs.

Physician-focused Payment Models (PFPMs)

PFPMs and CMMI. We believe that Congress, CMS, and STS membership are aligned in our desire to incentivize and implement a system of quality-based payment that rewards physicians for helping patients to make the best possible decisions about their care and achieve the best possible outcomes. However, we are concerned that CMS continues to misinterpret the intent of Congress as it pertains to the development of APMs.

CMS states that MACRA does not require PFPMs to meet the criteria to be an Advanced APM for purposes of the incentives for participation in Advanced APMs, and CMS does not propose to define PFPMs solely as Advanced APMs. Therefore, CMS states that stakeholders may propose to the PFPM Technical Advisory Committee (PTAC) either Advanced APMs or other PFPMs. CMS acknowledges that it received responses recommending that all proposed PFPMs selected for testing by CMS should be Advanced APMs, but CMS replies that it believes MACRA makes a distinction between APMs and Advanced APMs. STS continues to believe that Congress created the PFPM pathway in MACRA to establish transparency and efficiency in the CMMI process. STS, like many other organizations, endorsed MACRA based on the premise that we would have an opportunity to work with CMS on meaningful value-based payment models. STS believes that the intent of MACRA is to allow our members a choice between participating in either a revised system of fee-for service that would reward the provision of high quality care and improved patient outcomes *or* one or more specialty-specific payment models that would be appropriate to the patients they serve.

While physicians and/or medical specialty associations like STS have spent considerable time and effort preparing PFPM proposals to submit to the PTAC for evaluation and implementation, we are concerned about the ability of these proposals to provide benefit to our members and their patients under the current rulemaking. STS believes that the failure to recognize PTAC-approved PFPMs under the APM Incentive Program is not representative of Congressional intent. Within MACRA, establishment of the PTAC is under the title, “Promoting Alternative Payment Models.” The PTAC subsection’s purpose is stated as “increasing transparency of physician-focused payment models.” This legislative language makes it clear that Congress intended for PFPMs to provide an alternative, more transparent avenue for the development of qualified (now “Advanced”) APMs than currently exists. We firmly believe that Congress intended that the proliferation of multiple, specialty-specific APMs, no matter their origin, would help CMS to address the current problems in the current health care payment and delivery system. It is widely recognized that a one-size-fits-all approach to payment for all providers is inappropriate. We urge CMS to encourage the development and testing of multiple payment models and to help us to evaluate what works (and what does not) for different types of providers in different settings, as Congress intended.

PFPM Review Criteria

We agree with CMS’ general approach to outline the information that a submission to PTAC should include. We hope that CMS and PTAC will not prospectively define PFPMs, but rather

evaluate whether the proposed model adequately provided information in the areas included in CMS' proposal.

- ***PFPM Definition.*** *CMS proposes to require a PFPM to target physician services. To address physician services, proposed PFPMs may address such elements as physician behavior or clinical decision-making. CMS states that that APM Entities may be individual eligible clinicians, physician group practices (PGPs), or other entities, depending on the payment model's design but a PFPM must focus on physician services and contain either individual physicians or PGPs as APM Entities, although it may also include facilities or other practitioner types.*

  STS generally supports this part of CMS' proposed PFPM definition in that we believe that if APM Entities are not explicitly physician-owned, the entity should provide a means for physicians to influence the policies and goals of the organization.

- ***Payment Methodology.*** *CMS proposes a criterion that the PFPM proposal must pay APM Entities under a payment methodology that furthers the PFPM Criteria. CMS also states that the proposal must address how it is different from current Medicare payment methodologies and why the payment methodology cannot be tested under current payment methodologies.*

  STS continues to believe that the review criteria should provide flexibility and encourage innovation. We believe PFPMs will assume responsibility for the care (episode- condition- or procedure-based) of a population of patients; meet certain agreed upon quality measures; provide care for the determined services at agreed upon costs, and of course, be developed with intent to improve patient care and patient outcomes and reduce healthcare costs.

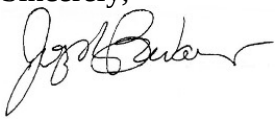
- ***Scope of Models****. CMS proposes to include in the first category a criterion that the PFPM must either aim to solve an issue in payment policy not addressed in the CMS APM portfolio at the time it is proposed or include in its design APM Entities who have had limited opportunities to participate in APMs. CMS states that physicians and practitioners whose opportunities to participate in other PFPMs with CMS have been limited to date include, for example, those who have not been able to apply for any other PFPM because one has not been designed that would include physicians and practitioners of their specialty. Simultaneously, CMS proposes that a proposed PFPM that includes multiple specialties may meet this criterion where a minimum of one of the specialties in the proposed PFPM is not currently being addressed by another APM. CMS states that its belief that this reflects the intent of MACRA where it specifically directs the Secretary to establish PFPM criteria, including models for specialist physicians.*

  We appreciate that CMS is attempting to ensure participation by as broad a proportion of the physician community as possible. However, **we request that CMS not be overly**

restrictive in that we believe that innovation in PFPMs could generate ideas about how to better address those issues that are perhaps already somewhat incorporated into existing models.

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

Sincerely,



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