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

Re: Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Mr. Slavitt:

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Centers for Medicare and Medicaid Services (CMS) Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models.

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.

A. The Merit-based Incentive Payment System

We appreciate the incredible challenge that CMS is facing in implementing the new Medicare Access and CHIP Reauthorization Act (MACRA). The benefit to CMS is that MACRA calls for the creation of a new Merit-based Incentive Payment System (MIPS) that relies on many of the existing CMS programs. However, we are also acutely aware that Congress did not endorse programs like Physician Quality Reporting System (PQRS) or Meaningful Use (MU) of Electronic Health Records (EHRs), or the Value Modifier (VM) wholesale. Rather, Congress acknowledged strengths and weaknesses of these programs. CMS is tasked with creating a foundation for MIPS that builds on the respective strengths of the various programs and eliminates problems like duplicative, burdensome, and costly reporting requirements. In general, we urge CMS to implement MIPS with an eye towards what will work best for

physicians and patients rather than how some of the more arcane aspects of the predicate programs can be adapted to fit the new MACRA mandate.

3. Quality Performance Category

Should we maintain all PQRS reporting mechanisms noted above under MIPS?

Yes, CMS should maintain all of the current PQRS reporting mechanisms to ensure flexibility for physicians with different needs. Familiarity with current reporting systems will facilitate acceptance and adoption of a more complex reporting system.

If so, what policies should be in place for determining which data should be used to calculate a MIPS EP's quality score if data are received via multiple methods of submission? What considerations should be made to ensure a patient's data is not counted multiple times?

In the context of capturing information on health care quality and outcomes, CMS should emphasize the value of clinical data from an audited registry, such as the STS National Database. Claims and other patient outcomes data can and should be made available to such registries so they can provide physicians with feedback on their performance and help improve care delivery and value overall. Providing an incentive for registry participation will encourage more physicians to report quality data via registry, which will improve the utility of the information CMS collects and eliminate redundancy.

A physician should not be allowed to report the same measure for the same patient across multiple mechanisms and have it count towards their score. However, there may be a need for a physician to report independent measures through multiple mechanisms and for those measures, in total, to count toward satisfying the quality measure reporting requirement. For example, an EP might identify a handful of clinically relevant e-specified measures that can be reported through an EHR, but also might identify a few other relevant measures that are not yet e-specified and can only be reported through a registry. CMS should recognize the reporting of measures across multiple reporting mechanisms in order to promote meaningful engagement and to encourage EPs to experiment with different options. Combining methods would also enable multi-specialty groups to use multiple registries to satisfy reporting.

Should we maintain the same or similar reporting criteria under MIPS as under the PQRS? What is the appropriate number of measures on which a MIPS EP's performance should be based?

Yes, CMS should maintain the same or similar reporting criteria as under PQRS.

Should we maintain the policy that measures cover a specified number of National Quality Strategy domains?

We urge CMS to reconsider the current PQRS requirement of 9 measures across 3 domains, which is an arbitrarily high standard that often results in reporting for the sake of reporting and

subsequent data that are of little value. In addition, CMS should allow measures to be assigned and counted towards meeting multiple domains and stakeholders should have input into the process of assigning a measure to a quality domain.

Should we require that certain types of measures be reported? For example, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?

We believe that an outcomes-based/data driven approach to care should be encouraged and supported, and that medical specialty associations are the only entities capable of generating relevant and clinically meaningful measures that are widely accepted by all stakeholders, including providers and patients. Outcomes measures that are created by the medical specialties and are founded in clinical data should be more heavily weighted and process measures should be used only when a direct correlation to quality improvement or patient safety can be demonstrated. CMS should not push forward with the development and maintenance of administrative claims based outcomes measures, which typically are poorly designed, under- or over- capture clinical information, and have attribution issues. Instead, CMS should encourage physicians to report on clinician-led and evidence-based outcome measures by recognizing and compensating for the increased effort required to report on patient outcomes.

Measures considered "high value" may differ by specialty or patient, as well as vary depending upon the intended purpose. Valid and reliable outcome measures could potentially lead to more direct measures of quality and their development by medical specialties should be encouraged and funded. There are a number of methodological issues that must be addressed by CMS before moving to assigning more weight to outcome measures, including risk adjustment and attribution. CMS should acknowledge that some patient scenarios may not lend themselves to measurement due to the evidence currently available, such as with measuring appropriateness and overuse criteria. Areas that fall in this grey zone are not good subjects or focus areas for measurement. Outcome measures at the physician level can also be particularly challenging to construct for two primary reasons—small sample sizes and the difficulty of identifying outcomes for which the physician can and should be held accountable (i.e. outcomes that are largely dependent on the quality of care received, not other factors). While STS agrees that outcomes measures are preferable and more relevant to overall quality assessment, we would strongly encourage CMS to prioritize the value of an individual measure in the clinical setting above the volume of measures a physician uses.

Should we require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender?

Yes, factors such as race, ethnicity, and gender are important to ensure equivalent quality and access to care is balanced among diverse patient populations. In addition, the ability to stratify data by demographic characteristics has been shown to demonstrate differences in risk. MACRA also requires CMS to provide qualified clinical data registries (QCDRs) with access to claims data which will help in this aspect of reporting. We urge the Secretary to exercise her authority under 42 USC §405(r)(9) to match Medicare claims data with data from the Social Security

Death Master File. This will allow QCDRs to better evaluate and analyze long-term patient outcomes.

For the CAHPS for PQRS reporting option specifically, should this still be considered as part of the quality performance category or as part of the clinical practice improvement activities performance category? What considerations should be made as we further implement CAHPS for all practice sizes? How can we leverage existing CAHPS reporting by physician groups?

The subjective CAHPS survey is unlikely to improve practice related to clinical outcomes. CMS should solicit feedback from patient advocacy groups to determine how to evaluate and value patient experiences. CAHPS participation may be valuable as a clinical practice improvement activity (CPIA) until such time as a more effective measure is available to be incorporated into the PQRS calculation.

How do we apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet our defined criteria? Should we maintain a Measure-Applicability Verification Process? If we customize the performance requirements for certain types of MIPS EPs, how should we go about identifying the MIPS EPs to whom specific requirements apply?

STS has a long history of maintaining and improving upon a robust list of NQF-endorsed quality measures. Any modifications to quality evaluation should not diminish the relative value of proven quality measurement undertaken on behalf of cardiothoracic surgeons.

What are the potential barriers to successfully meeting the MIPS quality performance category?

- Not having a sufficient set of relevant measures to choose from, or having too few patients to meet minimum standards for a statistically significant sample – CMS must continue to address measurement gaps and improve the existing set of measures. We reiterate our concern that CMS has not yet allocated MACRA-authorized funding toward this effort, and we urge the agency to do so as expeditiously as possible. We also remind CMS of the importance of ensuring that measure development is evidence-based and clinician-led.
- Arbitrarily high reporting thresholds – Requiring 9 measures across 3 NQS domains forces physicians to report on measures that are marginally relevant to their practice simply for the sake of reporting.
- Resources needed to access the reporting infrastructure.
- Adequate risk-adjustment.

What should CMS require in terms of testing of the qualified registry, QCDR, or direct EHR product, or EHR data submission vendor product? How can testing be enhanced to improve data integrity?

CMS should verify the submitting entity has mechanisms in place to ensure data quality and integrity. To avoid data integrity problems such as those CMS encountered with 2014 data collected via QCDRs and EHRs, CMS should require these entities to complete preliminary CMS-sponsored submission testing. Currently this is highly encouraged, but not required.

Should registries and qualified clinical data registries be required to submit data to CMS using certain standards, such as the Quality Reporting Document Architecture (QRDA) standard, which certified EHRs are required to support?

No. CMS should initially consider that using any method of electronic capture and transmission of quality data meets the intent of interoperability. It should not be required that CEHRT use only QRDA for capturing and transmitting data. Requiring CEHRT or QCDRs to only use QRDA will require time and resources to put in place.

As a starting point, CMS should provide ample notification, testing periods, and conversion guidelines to allow for previous users (whether QCDRs or others) who report data in the XML format to transition towards QRDA I or III formats in order to remain in programmatic compliance. We also believe that CMS should work with registries and other stakeholders to identify emerging standards that support a more scalable and flexible data reporting format.

Should CMS require that qualified registries, QCDRs, and health IT systems undergo review and qualification by CMS to ensure that CMS' form and manner are met? For example, CMS uses a specific file format for qualified registry reporting. The current version is available at: https://www.qualitynet.org/imageserver/pqrs/registry2015/index.htm. What should be involved in the testing to ensure CMS' form and manner requirements are met?

CMS should work with the submitting entity to ensure the integrity of the data by testing the data submission process. It would be beneficial for a QCDR to know at the beginning of a reporting year that its file format is correct. To accomplish this, CMS should provide new QCDR applicants with file specifications and access to the testing portal to new QCDRs prior to the CMS approval date (currently May). During that time, QCDRs should be able to test data format and validity.

When developing formats for data submission, 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, such as embedded risk adjustment. We are also aware that testing tools used for "form and manner" compliance have in the past been delayed, error-prone, or had multiple versions for use in testing vendor products. Health IT systems rely on these tools to validate their quality reporting system and any issues with these tools can promulgate errors down the development timeline or into the production environment.

What feedback from CMS during testing would be beneficial to these stakeholders?

CMS should communicate areas of failure so they can be corrected. It would be helpful for CMS to inform stakeholders of calculation errors. If testing requires any type of practice audit or

request for information from practices for data validation purposes, CMS should inform vendors of any communication to practices so that vendors can work with CMS to ensure that practices understand the purpose of the validation request.

In advance of, or concurrent with, updates to quality measures, CMS should clearly identify a timeline when testing tools will be available and at what point the version will be "static." Suggested milestones should be made available so that health IT vendors can incorporate measure testing into their products' timelines.

What thresholds for data integrity should CMS have in place for accuracy, completeness, and reliability of the data? For example, if a QCDR's calculated performance rate does not equate to the distinct performance values, such as the numerator exceeding the value of the denominator, should CMS re-calculate the data based on the numerator and denominator values provided? Should CMS not require MIPS EPs to submit a calculated performance rate (and instead have CMS calculate all rates)? Alternatively, for example, if a QCDR omits data elements that make validation of the reported data infeasible, should the data be discarded? What threshold of errors in submitted data should be acceptable?

CMS should provide feedback to the submitting entity on errors in the data which were submitted, allowing the EP to correct those errors and resubmit the data. This communication process should continue until all errors are corrected. If a QCDR or EHR vender is alerted to errors and does not make corrections in a reasonable period of time, it would be appropriate for CMS to discard the records where validation is not feasible or results in inconsistencies.

If CMS determines that the MIPS EP (participating as an individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet our data integrity standards, how should CMS assess the MIPS EP when calculating their quality performance category score? Should there be any consequences for the qualified registry, QCDR or EHR vendor in order to correct future practices? Should the qualified registry, QCDR or EHR vendor be disqualified or unable to participate in future performance periods? What consequences should there be for MIPS EPs?

CMS should provide feedback to a QCDR that has submitted incorrect information. The QCDR should be given the opportunity to correct the errors. However, the EP should not be penalized for the performance of the reporting mechanism. As a part of the QCDR application process, the QCDR should be able to demonstrate that reporting errors will not be replicated.

If adequate opportunities for initial testing, validation, and data correction are available and a QCDR, qualified registry or EHR vendor is still not adequately submitting correct and valid data, then the vendor should be placed on a corrective action plan. If, after a probationary period the vendor is still not adequately submitting data, the vendor should be excluded from future performance periods until it shows through testing that it is able to submit valid data. CMS must also recognize that there may be instances where the problem may reside with CMS and not just the vendor. In these instances, CMS should also hold physicians harmless from any penalties.

To help resolve potential and on-going issues, CMS should develop a root cause analysis toolkit to help vendors self-identify issues. This analysis should be conducted before corrective actions are initiated. This toolkit would help inform CMS and other vendors about new issues or ones that may become systemic. CMS should also make available an easily accessible appeals process and technical support for EPs that are experiencing reporting problems.

Under the MIPS, what should constitute use of CEHRT for purposes of reporting quality data?

At present, CEHRT does not provide the type of robust clinical quality information contained in the STS National Database, which is a QCDR. Until true EHR interoperability is achieved, we cannot begin to address problems of communication between EHRs and registries. Such a change is likely to require legislative intervention. In the interim, CMS should prioritize robust clinical information from a QCDR above CEHRT-reported data.

Instead of requiring that the EHR be utilized to transmit the data, should it be sufficient to use the EHR to capture and/or calculate the quality data? What standards should apply for data capture and transmission?

See above. STS would strenuously object to any proposal to use EHRs to capture quality data until such time as CEHRT can be required to be interoperable with clinical data registries.

4. Resource Use Performance Category

The RFI implies that CMS may keep all the current VM cost measures and then expand upon them. Unfortunately, the current measures have no clinical relevance for many physicians. In addition, some measures have no costs attributed to them and others attribute costs to physicians who have no ability to control that cost. As can be seen in CMS' QRURs (Quality and Resource Use Reports) and VM experience reports, the current cost and outcome measures also discriminate against physicians who treat high numbers of chronically ill and high risk patients because of inadequate risk adjustment.

Further, most of the VM measures were developed for primary care providers and are inappropriate for specialty physicians who do not treat Medicare beneficiaries using this family of Healthcare Common Procedure Coding System codes. The single code that may be applicable to surgeons is the discharge day management service (99315-6), but it fails to capture services provide by groups of cardiothoracic surgeons who work under a 90 global, which does not allow billing for the service. Much more fundamentally problematic is the concept of attribution which has not been solved for inpatient episodes of care. The current VM uses a plurality approach which will cause inappropriate allocation of resources for in-patient 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). Congress understood that the VM methodology is seriously flawed. That is why Congress called on CMS to revise the current episode-based measures and attribution process. CMS needs to

devote significant data analysis and resources to this effort in order to replace, not expand, the current VM cost measures. We look forward to working with CMS on this important task.

Are there additional cost or resource use measures (such as measures associated with services that are potentially harmful or over-used, including those identified by the Choosing Wisely initiative) that should be considered? If so, what data sources would be required to calculate the measures?

Medical specialty associations should be empowered 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. non-teaching) and the physician specialty.

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 would encourage CMS to work with all affected specialties to integrate such measures into the resource use category of MIPS.

How should we apply the resource use category to MIPS EPs for whom there may not be applicable resource use measures?

CMS should consult with medical specialty associations about how to redistribute points from this category if the specialty does not have enough resource use measures. CMS must also account for physicians and practices that do not have large enough Medicare populations to compute reliable scores.

What role should episode-based costs play in calculating resource use and/or providing feedback reports to MIPS EPs under section 1848(q)(12) of the Act?

In addition to their other flaws, current VM measures are irrelevant for many physicians—either because no patients get attributed to them or because the physicians have little to no opportunity to influence the costs that are attributed to them. If 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. Transparency and physician involvement in the development of these measures and the accompanying methodological decisions are critical. We strongly believe that CMS should create a process that provides an opportunity for thorough input from practicing physicians. Posting information on the CMS website about care episodes generated by a contractor and a handful of "experts" is insufficient.

How should CMS consider aligning measures used under the MIPS resource use performance category with resource use based measures used in other parts of the Medicare program?

CMS must first ensure that measures used in individual MIPS categories are valid, reliable, relevant, and actionable. Alignment across MIPS categories will need to be accomplished on a

case-by-case basis, taking into consideration site of service differences and in collaboration with relevant specialties. While episode measures should eventually include both costs and outcomes, achieving this goal will require that CMS work with relevant medical specialty associations to identify specific outcomes related to the condition or service being measured rather than some general measure such as all cause readmissions. Per above, CMS is required to begin to provide QCDRs with access to Medicare claims data. This will also be an essential step in helping to align the various measures across all programs. We ask CMS to begin to implement this policy as soon as possible and ask that the Secretary authorize the authority granted under 42 USC §405(r)(9) to combine these data with death information from the Social Security Death master File.

What peer groups or benchmarks should be used when assessing performance under the resource use performance category?

Due to the diversity of physician practices even within the same specialty, making accurate comparisons of physicians' performance will require far more detailed delineation of specialty and sub-specialty area(s) of expertise and/or site of practice than is currently conducted by either Medicare or private payers. While we appreciate CMS' efforts to adjust for specialty in the VM program, more work is needed.

5. Clinical Practice Improvement Activities Category

STS supports many of the examples of CPIAs that were included in MACRA. In particular, we are grateful that participation in a QCDR, use of surgical checklists, and practice assessments related to maintenance of certification were included as CPIAs. We would suggest that tools like the STS Risk Calculator be included among the shared decision-making mechanisms mentioned in the statute. The STS Risk Calculator allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

While we support the inclusion of CPIAs in the MIPS performance score, we also endorse the relative weight of this component as compared to the other MIPS provisions. We would note that the statute provides little guidance on how to implement the CPIA requirement, and caution CMS not to unintentionally overburden physicians with check-the-box requirements as they work to achieve high scores on the other, more heavily-weighted components. Credit should be given for adoption of new clinical practice improvement activities and maintenance of existing activities that have been shown to add value and quality. STS suggests that physician activities involved in meeting the Part IV requirements of Maintenance of Certification, 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, be strongly considered as qualifying activities for CPIA. Physicians should not be required to complete one activity in every category but select those categories that best fit their practices and the types of activities which are appropriate for each specialty are determined by that specialty's Board under the oversight and approval of ABMS. While the activities themselves should yield positive

changes that will benefit patients, making this aspect of the MIPS program too rigid and too much of a one size fits all specialties could have very negative impacts on physicians who are trying to acclimate to a new payment structure.

Moreover, physicians and other eligible professionals should be given credit for CPIAs in which they are currently engaged, including those that are mandated or encouraged by Medicare and other government programs. This would include a long list of activities such as:

- Consulting appropriate use criteria.
- Participation in CMS's Million Hearts Campaign, Cardiovascular Disease Risk Reduction Model, Oncology Care Model, Transforming Clinical Practice Initiative.
- Participation in relevant practice improvement activities facilitated by each state's Quality Improvement Organization.
- Other activities associated with the six practice improvement categories Congress specifically called for in the MACRA include the following types of activities:
    - *Expanded practice access*: Same day appointments for urgent needs; after-hours clinician advice – using secured messaging, patients can ask questions of their provider that is well documented in the patient record; remote monitoring of chronic conditions; establish policy allowing patients with emergencies to walk-in during certain established hours; Saturday and expanded hours for clinics to increase access; Use of satellite offices to bring services to patients. Serving on call in an emergency department.
    - *Care coordination*: Timely communication of test results; Ability of patients to electronically access their own medical record; Ability of practice to receive and act upon fax or email from referring doctor; Ability to provide patients with printed copy of test results; Billing chronic care management or transitional care management codes.
    - *Beneficiary engagement*: Practice provides patients with option to download or have mailed medical history forms to fill out prior to first appointment; Training of patients in proper appropriate administration of medications and proper use and maintenance of durable medical equipment and various remote monitoring devices and home testing products. Use of decision trees and questionnaires to engage patients in shared decision making on their medical care. Patient flyers for specific conditions. Nutritional counseling.
- Various activities of organizations representing physicians and medical groups should also be recognized as practice improvement. This would include accredited continuing medical education, board-certification-related activities and other initiatives aimed at improving practice such as opioid prescriber training and provision of medication-assisted treatment of opioid use disorders.
- Administration of CAHPS or other patient experience and satisfaction surveys should be considered as a CPIA rather than a quality measure.
- Participation in designated private payer clinical practice improvement activities.
- Participation in self-assessment and self-examination (e.g. SESATS).
- Maintenance of Certification Part IV.

Should EPs be required to attest directly to CMS through a registration system, Web portal or other means that they have met the required activities and to specify which activities on the list they have met? Or alternatively, should qualified registries, QCDRs, EHRs, or other health IT systems be able to transmit results of the activities to CMS?

At the outset of the MIPS program, physicians should be allowed to attest to their completion of the requisite CPI activities annually via a web portal. STS would be willing to work with CMS to develop a mechanism by which QCDRs being used to report on the quality portion of the MIPS program can be used to report on successful completion of CPIAs. Such a project would require additional resources from CMS but will minimize the reporting burden to EPs and maximize the success of the CPIA program.

What information should be reported and what quality checks and/or data validation should occur to ensure successful completion of these activities?

Per above, we believe that CMS should work with QCDRs to develop a CPIA reporting process that will include data validation and quality checks.

How often providers should report or attest that they have met the required activities?

Yearly.

What threshold or quantity of activities should be established under the clinical practice improvement activities performance category? For example

- ***Should performance in this category be based on completion of a specific number of clinical practice improvement activities, or, for some categories, a specific number of hours?***

  CPIA performance should be based on completion or ongoing participation in a specified number of clinical improvement activities rather than hours.

- ***Should the threshold or quantity of activities increase over time?***

  No.

Should performance in this category be based on demonstrated availability of specific functions and capabilities?

EPs should be presented with enough choices so that a menu of CPIA options exists each year to ensure the opportunity for successful completion.

How should the various subcategories be weighted? Should each subcategory have equal weight, or should certain subcategories be weighted more than others?

At least initially, all CPIAs should be weighted equally. Over time, CMS could consider more rigorous scoring methodologies and weighting by activity, including assigning values based on the type of CPIA. This weighting process should be accomplished in collaboration with the relevant medical specialties via their medical specialty associations.

How should we define the subcategory of participation in an APM?

EPs attempting to participate in an alternative payment model (APM) should be required to attest. Successful participation in an APM will be verified through the APM payment mechanism. In order for the new models in which physicians participate to be counted towards their CPI score, the models must be able meet the MACRA definition of an APM and **NOT** an approved eligible alternative payment model entity (EAPM). As discussed below, CMS must establish a clear means for physician-focused payment model (PFPM) proposals to be approved for implementation as qualified APMs. The definition of the APM subcategory under MIPS should include physician or other eligible professional participation in an APM "sponsored" by a commercial payer or Medicaid.

How should the clinical practice improvement activities performance category be applied to EPs practicing in these types of small practices or rural areas?

CMS should allow for the broadest possible interpretation of CPIA participation and should ensure that there are a number of free or low-cost CPIA choices.

What best practices should be considered to develop flexible and adaptable clinical practice improvement activities based on the needs of the community and its population?

Initially, CMS should allow for the broadest definition of activities that qualify as a CPIA, and, simultaneously work with stakeholders to identify best practices based on community and population needs.

6. Meaningful Use of Certified EHR Technology Performance Category

It is extremely important that CMS make changes to the current MU program prior to MACRA implementation to ensure that MU is achievable and meaningful for all physicians, including specialists. CMS should reopen MU Stage 3 to realign the program and take time to evaluate whether providers are successful under the Stage 2 Modifications rule. In addition, CMS should focus on increasing the functional interoperability among various EHRs and between EHRs and clinical data registries to ensure meaningful use is a program that improves healthcare, and not another unnecessary regulatory burden on providers.

Should the performance score for this category be based solely on full achievement of meaningful use? For example, an EP might receive full credit (for example, 100 percent of the

allotted 25 percentage points of the composite performance score) under this performance category for meeting or exceeding the thresholds of all meaningful use objectives and measures; however, failing to meet or exceed all objectives and measures would result in the EP receiving no credit (for example, zero percent of the allotted 25 percentage points of the composite performance score) for this performance category. We seek comment on this approach to scoring.

No, if providers are attesting for MU and meet a certain percentage of the measures, there should be a way for them to get credit for the percentage they were able to complete.

Should CMS use a tiered methodology for determining levels of achievement in this performance category that would allow EPs to receive a higher or lower score based on their performance relative to the thresholds established in the Medicare EHR Incentive program's meaningful use objectives and measures? For example, an EP who scores significantly higher than the threshold and higher than their peer group might receive a higher score than the median performer. How should such a methodology be developed? Should scoring in this category be based on an EP's under- or over-performance relative to the required thresholds of the objectives and measures, or should the scoring methodology of this category be based on an EP's performance relative to the performance of his or her peers?

We strongly disagree with the tiered approach. Using a performance-based/tiered methodology for the MU component of the composite score would unfairly penalize certain participants based on circumstances largely outside their control such as subspecialty/scope of practice, location/setting, business environment/competition, and patient population, among others. Moreover, many MU participants satisfy the requirements of the program, in part, through meeting the prerequisites of available exclusions from certain measures rather than satisfying the measures themselves. Exclusions should qualify as fully meeting the measure and not result in a lower score for the MU component.

How should hardship exemptions be treated?

There should be significant flexibility in the type of hardship exemption that are offered for MU. If a provider chooses to file for a hardship emption, (s)he should not be penalized in the MU performance category.

<u>7. Other Measures</u>

Any measures used to assess a providers' performance should be specifically relevant to that provider and the conditions the physician treats. They should be limited to measures that the provider can control and should not depend on another provider or patient's successful completion of a given activity or function.

What types of measures (that is, process, outcomes, populations, etc.) used for other payment systems should be included for the quality and resource use performance categories under the MIPS?

Per the comments above, when available, outcomes measures are preferable. Physicians reporting on outcomes measures should have an advantage over those reporting solely process or other types of measures.

How could we leverage measures that are used under the Hospital Inpatient Quality Reporting Program, the Hospital Value-Based Purchasing Program, or other quality reporting or incentive payment programs? How should we attribute the performance on the measures that are used under other quality reporting or value-based purchasing programs to the EP?

Measures should overlap with performance measures to ease the burden of data collection

What types of global and population-based measures should be included under MIPS? How should we define these types of measures?

CMS should exclude population-based measures for surgical specialists which do not treat "populations" of patients.

What data sources are available, and what mechanisms exist to collect data on these types of measures?

Existing clinical data registries should be leveraged to the extent possible. However, resources will need to be made available for registry development and maintenance. Specialties that have developed such data sources should be given priority support and begin to move forward rather than awaiting other providers to "catch up."

8. Development of Performance Standards

We strongly urge CMS to make every effort to reduce the gap between the performance and the payment year.

Which specific historical performance standards should be used? For example, for the quality and resource use performance categories, how should CMS select quality and cost benchmarks? Should CMS use providers' historical quality and cost performance benchmarks and/or thresholds from the most recent year feasible prior to the commencement of MIPS? Should performance standards be stratified by group size or other criteria? Should we use a model similar to the performance standards established under the VM?

It is important that all performance standards are risk-adjusted. The STS Risk Calculator allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates 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. CMS should utilize the robust clinical information contained in the STS National Database and our proven risk-calculation methodology to ensure the accuracy and relevance of performance categories and benchmarks.

CMS should use the first year of MIPS performance as a baseline for future benchmarks in out years. Although the law requires CMS to "consider" historical performance standards, it stops short of requiring the agency to "use" historical standards. Given the imperfect and still changing nature of the current incentive programs, it is preferable to use some future year as the basis for determining historical performance. In the interim, CMS should consult with medical organizations to identify potential sources of data, including QCDRs, for historical performance standards. Further, since a very large percentage of physicians will have VM scores that are not based on actual data and many others will have scores that bear little relevance to their own performance, the VM would be an inappropriate foundation of performance under MIPS. In addition, CMS should refine the VM specialty mix adjustments to ensure that performance comparisons are applied to groups of similar characteristics. These calculations should be very clear and highly transparent so that physicians can understand them and be successful in MIPS.

For the clinical practice improvement activities performance category, what, if any, historical data sources should be leveraged?

- Existing clinical data registries,
- Medical device and pharmaceutical industry data,
- Private insurer data.
- American Board of Medical Specialties Maintenance of Certification information

How should we define improvement and the opportunity for continued improvement? For example, section 1848(q)(5)(D) of the Act requires the Secretary, beginning in the second year of the MIPS, if there are available data sufficient to measure improvement, to take into account improvement of the MIPS EP in calculating the performance score for the quality and resource use performance categories.

CMS must ensure that the methodology for determining "improvement" is statistically sound, risk adjusted, and transparent. Participation in a quality improvement project may be a reasonable benchmark for improvement until the program has collected enough data.

In addition, it is essential that CMS bear in mind that MIPS is not designed to be a tournament-style program CMS is required to disclose what the benchmarks are prior to the start of a performance period. As such, generous education and outreach must be used in concert with performance standards development so that groups and providers know exactly who their peers are and what their goals will be.

How should CMS incorporate improvement into the scoring system or design an improvement formula?

Individual practice and surgeon statistics in the STS National Database provide the greatest opportunity to measure and achieve performance improvement. If a practice/surgeon is identified

as an outlier for a particular metric, this is an opportunity for improvement which will be measurable with the database. Still, those with exceptionally bad performance could achieve considerable improvement while a surgeon who is already a top tier performer might find it very difficult to improve. For that reason, the methodology must take into account both achievement and improvement.

What should be the threshold(s) for measuring improvement?

Improvement thresholds should be established on a measure-by-measure basis using current literature and scientific evidence.

How would different approaches to defining the baseline period for measuring improvement affect EPs' incentives to increase quality performance? Would periodically updating the baseline period penalize EPs who increase performance by holding them to a higher standard in future performance periods, thereby undermining the incentive to improve? Could assessing improvement relative to a fixed baseline period avoid this problem? If so, would this approach have other consequences CMS should consider?

CMS should consider using a four-year, rolling average for baseline calculations. With time, the baseline will flatten as areas for significant improvement become less fruitful. At a defined endpoint, either maintenance or lack of deviation from the baseline should become a standard of excellence. Improvement and achievement are both important factors.

Should CMS use the same approach for assessing improvement as is used for the Hospital Value-Based Purchasing Program? What are the advantages and disadvantages of this approach?

A principle weakness of the value-based purchasing (VBP) program to date has been the relative opacity of the process. Physicians have no sense of their relative performance until the final results are tabulated. This leaves them with little opportunity to address problems until it is too late.

Should CMS consider improvement at the measure level, performance category level (that is, quality, clinical practice improvement activity, resource use, and meaningful use of certified EHR technology), or at the composite performance score level?

A weighted composite score is preferred as it takes into account all levels of measurement. Each level can be measured and scored independently and then a composite score obtained using a weighted domain formula as is used in hospital VBP. This composite can then be applied to a transfer function which will yield a payment adjuster.

Should improvements in health equity and the reductions of health disparities be considered in the definition of improvement? If so, how should CMS incorporate health equity into the formula?

No, health disparities and health equity should not be part of the "improvement" definition. Geography (practitioner location) and referral patterns for referral based practitioners have an effect which could unintentionally negatively affect the EP.

In the CY 2016 PFS proposed rule (80 FR 41812), the Secretary proposed to publicly report on Physician Compare an item-level benchmark derived using the Achievable Benchmark of Care (ABC^{TM}) methodology. [2] We seek comment on using this methodology for determining the MIPS performance standards for one or more performance categories.

ABC™ benchmarks are demonstrably inferior to those that are based in an established registry with statistically sound methodology. CMS cannot subject all Medicare physicians to a methodology that can accommodate the lowest common denominator. It deprives those who know how to measure health care quality and improvement of the ability to make meaningful changes.

9. Flexibility in Weighting Performance Categories

Are there situations where certain EPs could not be assessed at all for purposes of a particular performance category? If so, how should we account for the percentage weight that is otherwise applicable for that category? Should it be evenly distributed across the remaining performance categories? Or should the weights be increased for one or more specific performance categories, such as the quality performance category?

Medical specialty associations are in the best position to decide the assessments of EP performance based on practice patterns.

Generally, what methodologies should be used as we determine whether there are not sufficient measures and activities applicable and available to types of EPs such that the weight for a given performance category should be modified or should not apply to an EP? Should this be based on an EP's specialty? Should this determination occur at the measure or activity level, or separately at the specialty level?

Yes, this should be done at the EP specialty level for consistency and equity.

What case minimum threshold should CMS consider for the different performance categories?

This would depend on the nature of the EP specialty.

What safeguards should we have in place to ensure statistical significance when establishing performance thresholds? For example, under the VM one standard deviation is used. Should we apply a similar threshold under MIPS?

Many QCDRs have developed statistical methods to evaluate performance, and these methods should be maintained for measures under MIPS.

10. MIPS Composite Performance Score and Performance Threshold

What minimum case size thresholds should be utilized? For example, should we leverage all data that is reported even if the denominators are small? Or should we employ a minimum patient threshold, such as a minimum of 20 patients, for each measure?

The smaller the denominator for the sample, the larger the standard error. CMS should consider the threshold to limit the size of the standard error to a certain percentage of the observed metric.

11. Public Reporting

In the CY 2016 PFS proposed rule (80 FR 41809), we indicated that we will continue using a minimum 20 patient threshold for public reporting through Physician Compare of quality measures (in addition to assessing the reliability, validity and accuracy of the measures). An alternative to a minimum patient threshold for public reporting would be to use a minimum reliability threshold. We seek comment on both concepts in regard to public reporting of MIPS quality measures on the Physician Compare Web site.

In many cases, specialties are already publically reporting meaningful quality information from an established registry with statistically sound methodology. At the same time, CMS' public reporting program provides confusing information that is of limited utility to patients. CMS should develop a process through which it can capitalize on this important work. Such collaboration will prevent misinformation and better serve Medicare beneficiaries.

Before CMS publically reports on MIPS performance, we would suggest that CMS first work on carefully designing the MIPS program, accrue a minimum foundation of data using the new system (at least 2 years); confidentially share those data with practicing physicians via clear, easy to understand feedback reports. Simultaneously, CMS should conduct research into what information and reporting formats are most valuable to consumers and physicians and what existing public reporting scores and methodologies already exist. Only after this work is complete should CMS transition to the public reporting of physician performance data.

When making decisions about whether a measure is ready for public reporting, CMS should continue to adhere to its current policy of selecting only those measures which prove to be valid, reliable, and accurate; are deemed statistically comparable; meet a minimum sample size of patients; are not first-year measures; and have proven, through concept testing, to be of value to consumers. With regard to appropriate minimum patient thresholds, CMS should keep in mind that these thresholds may vary across measures and specialties. It is, perhaps, better to focus on

ensuring that a specific reliability score is obtained, rather than focusing on minimum sample sizes.

Further, unlike current CMS practice, physicians should be given the opportunity to comment on Physician Compare Technical Expert Panel recommendations and we urge CMS not to use raw file downloadable databases to present data to the public. We are concerned that such data are misleading, misinterpreted, and often misused by the public.

Should CMS include individual EP and group practice-level quality measure data stratified by race, ethnicity and gender in public reporting (if statistically appropriate)?

All patients deserve equal access to high quality care and stratifying data might help to identify and reduce disparities in care. Nevertheless, CMS first needs to address more foundational challenges related to public reporting (e.g., appropriate sample sizes, accurate attribution, and meaningful formats). Attempting to stratify data before these foundational issues are addressed would only further complicate the endeavor and produce potentially inaccurate, more confusing, and less actionable data for physicians and the public. Targeting health disparities at the individual physician level may not be practical due to small sample sizes and other methodological issues that might result in misleading and confusing information for the public. Targeting disparities is a larger system goal that might need to be addressed with systems-level measures, not measures that are reported at the level of the individual practitioner.

12. Feedback Reports

CMS must provide ongoing, real-time feedback on performance and should consult stakeholder groups continuously to determine the best presentation and most meaningful format for sharing ongoing, actionable performance feedback information with physicians and practices. Benchmarking and attribution methodologies must be transparent and easy to interpret. CMS must provide a fair and transparent process for providers to appeal findings in feedback reports, and should lengthen the appeals process to at least 90 days.

What types of information should we provide to EPs about their practice's performance within the feedback report? For example, what level of detail on performance within the performance categories will be beneficial to practices?

Provide data at the EP level compared to like physicians.

Would it be beneficial for EPs to receive feedback information related to the clinical practice improvement activities and meaningful use of certified EHR technology performance categories? If so, what types of feedback?

National comparatives on similar practice improvement initiatives would be beneficial. EPs should be informed about what they can do to improve on meaningful use.

With what frequency is it beneficial for an EP to receive feedback? Currently, CMS provides Annual Quality and Resource Use Reports (QRUR), mid-year QRURs and supplemental QRURs. Should we continue to provide feedback to MIPS EPs on this cycle? Would there be value in receiving interim reports based on rolling performance periods to make illustrative calculations about the EP's performance? Are there certain performance categories on which it would be more important to receive interim feedback than others? What information that is currently contained within the QRURs should be included?

Annually.

Should the reports include data that is stratified by race, ethnicity and gender to monitor trends and address gaps towards health equity?

CMS should defer to the medical specialty associations who have already developed this methodology.

What types of information about items and services furnished to the EP's patients by other providers would be useful? In what format and with what frequency?

No, this should not be included.

B. Alternative Payment Models

General Comments
We believe that Congress, CMS, and the 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 may be misinterpreting the intent of Congress as it pertains to the development of APMs.

Over the past two years, STS leaders had the opportunity to testify twice before the House Committee on Energy and Commerce. Each time STS testified (June 6, 2013; Jan. 22, 2015), we encouraged Congress to *let us go first* to demonstrate how specialty-driven APMs can work. Now that we are on the precipice of development and implementation, the path forward seems less clear.

Congress created the PFPM pathway in MACRA to establish transparency and efficiency in the Centers for Medicare and Medicaid Innovation (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 the MACRA legislation is to allow our members a choice between participating in a revised system of fee-for service that would reward them for providing high quality care and improving patient outcomes or design and implement one or more specialty-specific payment models that would be appropriate to the patients they treat.

While physicians and/or medical specialty associations like STS have spent considerable time and effort preparing PFPM proposals to submit to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for evaluation and implementation, it is unclear whether CMS intends to reward those efforts. On multiple occasions since the publication of this RFI, representatives speaking on behalf of CMS have maintained that CMS "has no obligation" to implement any APM proposals submitted to the PTAC. STS believes that this is not representative of Congressional intent. 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.

Further, in the RFI, CMS has asked a number of important questions – the answers to which will protect Medicare beneficiaries, the integrity of Medicare payments, and the physicians who rely on Medicare payments. However, we would suggest to CMS that, just as there is no single payment model that is appropriate for all providers, there is no single right answer to most of these questions. Instead, we believe each specialty-driven APM should be prepared to answer these questions in the context of the specific proposal. Models that have not addressed these questions may not be positively evaluated by the PTAC or implemented by CMS until revisions are made. For example, CMS has the opportunity to allow different providers in different group settings, hospitals, and specialties to demonstrate how best to navigate patient and payment attribution for their individual practices yet the RFI asks how *ALL* APM patients/payments should be attributed. It is unclear why CMS would want to limit payment options before physician-led APMs even get off the ground. However, if the models are able to address these questions and are able to demonstrate how they will successfully meet the needs of CMS then they should be approved by the Secretary and evaluated though a demonstration program run by CMMI.

STS considers the PTAC process an opportunity to try out ideas and learn from outside experts. We hope that the PTAC process as well as the evaluation criteria will ensure that the Committee has an opportunity to engage with entities that develop PFPMs and provide them feedback. CMS and our health system at large will miss out on a great opportunity if the PTAC simply approves or rejects PFPMs with no context or explanation. PFPM proposals can and should be given the opportunity to be reviewed and perfected before they are passed on to the Secretary. If PTAC is allowed to function in this way, it would be in the best interest of CMS, Medicare beneficiaries and providers, and the health system at large. CMS and the PTAC should work collaboratively with medical specialty associations and other organizations to develop proposals, provide feedback on drafts, and provide data up-front to help in modeling. Ideally, PTAC's recommendations to CMS should include directions on how to implement any PFPM in which the Committee supports.

1.Information Regarding APMs
b. Payment Incentive for APM Participation

It is important for CMS to allow maximum flexibility for proposed APMs to outline various organizational structures to serve as EAPM entities and different pathways by which revenues might flow through the EAPM entity. CMS should not require all EAPM entities to be organized the same way, nor should it require every physician participating in an APM to obtain a new APM identification number. 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.

It seems likely that many payments under an APM will be made to an entity rather than directly to an eligible physician. In order to ensure that the physicians participating in the APM are able to influence the governance policies of the APM entity, CMS should require such entities to provide for meaningful participation in governance by physicians whether or not the APM entity is a physician-owned organization.

Claims for Medicare physician services are generally submitted by an organization with a taxpayer identification number (TIN) comprising one or more physicians that are separately identified through their National Provider Identifier (NPI). If Medicare makes payments to a TIN for an APM involving multiple physicians, the APM entity should then take responsibility for providing information to CMS on the revenue shares attributable to each APM physician. This approach has several advantages:

- If the APM entity is paying participating physicians for high-value services that are either not covered or not separately payable by Medicare's traditional payment systems, it can appropriately include or exclude these services in its internal calculations of each physician's revenue or patient shares under the APM.

- If physicians participating in the APM are not being paid on a fee-for-service basis, the APM entity can determine the best way to attribute revenue or patient shares to different participating physicians.

- If some of the physicians who bill for fee schedule services through the APM entity's TIN are APM participants and some are MIPS participants, the APM entity can manage the reporting requirements for the different programs.

Another key issue for APM Entities will be determining the methods for establishing whether physicians participating in an APM have or have not met the MACRA participation thresholds to qualify for the lump sum incentive payments. These methodologies should be left to the discretion of the APM entities, but APM entities should be required to describe the method they will use when they submit an APM proposal.

How should CMS define "services furnished under this part through an EAPM entity"?

The services furnished under an APM will necessarily vary depending on the APM that is proposed. The APM should define these services as a part of the APM proposal.

What policies should the Secretary consider for calculating incentive payments for APM participation when the prior period payments were made to an EAPM entity rather than directly to a QP, for example, if payments were made to a physician group practice or an ACO? What are the advantages and disadvantages of those policies? What are the effects of those policies on different types of EPs (that is, those in physician-focused APMs versus hospital-focused APMs, etc.)? How should CMS consider payments made to EPs who participate in more than one APM?

Since the answer to this question will vary depending on the particular model, CMS should allow for considerable flexibility. In some cases, the number of patients treated may be appropriate, while in another situation payments made may give a better picture of participation. The APM incentive payment should be based on the value of services that the physician actually provided, not on value-based payments that take bonuses or penalties into consideration.

What policies should the Secretary consider related to estimating the aggregate payment amounts when payments are made on a basis other than fee-for-service (that is, if payments were made on a capitated basis)? What are the advantages and disadvantages of those policies? What are their effects on different types of EPs (that is, those in physician-focused APMs versus hospital-focused APMs, etc.)?

A fundamental principle of all APMs is that they will advance coordination among those involved in providing health care to a patient population. 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 establishes stringent requirements, this is likely to inhibit that goal. The distribution of payments to providers should be the result of decisions made at the model level. However, CMS should expect that model proposals explain how revenues will be distributed.

What types of data and information can EPs submit to CMS for purposes of determining whether they meet the non-Medicare share of the Combination All-Payer and Medicare Payment Threshold, and how can they be securely shared with the federal government?

Given that EPs might be reluctant to share their non-Medicare payment information with CMS and the fact that this combination option does not start until 2021, we recommend that CMS offer the option for physicians to *attest* to how much non-Medicare payment they receive instead of providing actual data. CMS has a history of allowing *attestation* in the beginning stages of programs.

Further, the process for submitting this information should not add administrative burden to APM participants. After the initial implementation/attestation phase, the APM may identify ways to utilize existing clinical data registries or other sources in reporting these data.

c. Patient Approach

As above, these details should be contained within the specific APM proposals rather than handed down by CMS at the outset. Eligible physicians should not be required to use either the patient or payments approach. They should retain the option to use the patient approach to calculating the share of their Medicare "business" that is attributable to one or more APMs instead of the revenue approach. Most physicians manage certain proportions of patients with one of several different conditions. In some cases, it may be simpler to determine what proportion of a physician's patient population has conditions or episodes covered by APMs than to calculate revenues attributable to APMs. However, APMs are also likely to be designed around higher-cost conditions so some physicians may be more likely to meet the MACRA thresholds using the revenue approach.

d. Nominal Financial Risk

What is the appropriate type or types of "financial risk" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an EAPM entity?

In general, risk should only be associated with those aspects of care over which a provider has control. APMs are intended to drive the health system away from a fee-for-service paradigm into a pay-for-quality approach. The hazard of overemphasizing the financial risk requirement is that no providers will enter into APMs. For example, Dartmouth-Hitchcock, the birthplace of ACOs recently dropped out of the Pioneer program because it was unable to meet the savings and performance goals. CMS should start low and increase risk slowly over time.

CMS should also consider factoring the investment in model development 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. 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.

What is the appropriate level of financial risk "in excess of a nominal amount" under section 1833(z)(3)(D)(ii)(I) of the Act to be considered an EAPM entity?

Physicians will be much more willing to take accountability for costs that they can influence through their own performance, such as the costs of preventable complications, than taking on risk for the total cost of care for a large patient population. "More than nominal financial risk" should be defined in a way that allows physicians to take accountability for the services they can truly influence instead of requiring physicians to take responsibility for total Medicare spending

on every health problem and service their patients receive. Also, it is important that CMS allow sufficient time to achieve savings goals and not expect them to be reached in the early phases of model implementation.

What is the appropriate level of "more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures" that should be required by a non-Medicare payer for purposes of the Combination All-Payer and Medicare Payment Threshold under sections 1833(z)(2)(B)(iii)(II)(cc)(AA) and 1833(z)(2)(C)(iii)(II)(cc)(AA) of the Act?

See previous answer.

What are some points of reference that should be considered when establishing criteria for the appropriate type or level of financial risk, e.g., the MIPS or private-payer models?

It will vary according to the model. CMS should exercise flexibility.

f. Regarding EAPM entity Requirements

What entities should be considered EAPM entities?

First, CMS must establish a process whereby PFPMs proposed to the PTAC have a clear and transparent pathway to adoption. In terms of basic criteria for adoption, EAPMs should: 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. EAPMs should be developed with the intent to improve patient care and patient outcomes and reduce healthcare costs. If APM entities are not physician-owned, the entity should provide a means for physicians to influence the policies and goals of the organization.

CMS should place as few prospective restrictions as possible on new EAPMs proposals. Instead, each proposal should be evaluated on its overall merits. CMS should also resist imposing one-size-fits-all criteria on all possible EAPMs.

What criteria could be considered when determining "comparability" to MIPS of quality measures used to identify an EAPM entity? Please provide specific examples for measures, measure types (for example, structure, process, outcome, and other types), data source for measures (for example, patients/caregivers, medical records, billing claims, etc.), measure domains, standards, and comparable methodology.

The agreed upon measures need to be meaningful, specialty-specific, and lead to better patient care. STS maintains the most NQF-endorsed quality measures of any other entity. 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. It is absolutely essential to the success of APMs that the provider comprehends the measurement process in order to understand how they can improve. The reporting process should be as

streamlined as possible. QCDRs, such as the STS National Database, should be used wherever possible.

Selection of quality measures for an APM should be based on the goals and design of the APM. An incentive to APM participation is that the provider will not be required to be measured under MIPS. Trying to make APM measures comparable to MIPS seems to defeat the purpose. If there are any MIPS measures related to the condition or disease that is managed within the APM, the APM entity should consider whether or not to use those measures. It is important that quality measure reporting for an APM be no more burdensome than under MIPS. It is also important to focus on harmonizing measures so that there are not different ways of measuring the same thing that must be used for MIPS vs. APMs and Medicare vs. other payers.

What criteria could be considered when determining "comparability" to MIPS of quality measures required by a non-Medicare payer to qualify for the Combination All-Payer and Medicare Payment Threshold? Please provide specific examples for measures, measure types, (for example, structure, process, outcome, and other types), recommended data sources for measures (for example, patients/caregivers, medical records, billing claims, etc.), measure domains, and comparable methodology.

See previous answer.

What components of certified EHR technology as defined in section 1848(o)(4) of the Act should APM participants be required to use? Should APM participants be required to use the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs or should CMS other consider requirements around certified health IT capabilities?

The use of certified health IT in APMs should follow a patient-centered outcomes approach rather than one that is tied to process measures and "counting clicks" to meet thresholds. The "use" of CEHRT should be outlined within the APM proposal. As many proposals for new APMs will be developed by stakeholders and not CMS, the traditional concept of CEHRT must be adjusted to allow the development of specialized health IT modules that support the goals of APMs.

What are the core health IT functions that providers need to manage patient populations, coordinate care, engage patients and monitor and report quality? Would certification of additional functions or interoperability requirements in health IT products (for example, referral management or population health management functions) help providers succeed within APMs?

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.

How should CMS define "use" of certified EHR technology as defined in section 1848(o)(4) of the Act by participants in an APM? For example, should the APM require participants to

report quality measures to all payers using certified EHR technology or only payers who require EHR reported measures? Should all professionals in the APM in which an eligible alternative payment entity participates be required to use certified EHR technology or a particular subset?

We do not believe that quality measures can be adequately reported using EHRs currently. Such a requirement would deprive APM participants the ability to use the most meaningful quality measurement and improvement tools to implement their APMs.

2. Physician-Focused Payment Models

It is critical that the MACRA regulations establish a clear and transparent pathway for models to be proposed to the PTAC and for those models that are recommended by the PTAC to HHS to be implemented by CMS as qualified APMs. CMS has stated that it has no obligation to test models that are recommended by the PTAC. We strongly disagree and believe that this extremely narrow perspective is not in agreement with the intent of the legislation. For MACRA to succeed in reforming the delivery of care and improving value for patients and the Medicare Trust Funds, CMS must be willing to give serious consideration to proposed PFPMs that are approved by the PTAC and support their implementation, as intended by the law. 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 APMs than currently exists.

Since model development is likely to require a substantial investment in time and money, there should be a process whereby PFPM applicants can receive feedback during the development process of their model so they can assess whether they are on the right track or if they need to make changes. At the very least, if a model is not accepted, the PTAC/CMS should be required to give the rationale for rejecting the model and provide suggestions for improving the model. Otherwise PFPM applicants stand to lose their entire investment.

Implementation pathways should not be limited to small tests in a few communities. The APM incentive payments available under MACRA are for services furnished through an EAPM entity during a six-year period only: 2019 through 2024. Physicians in all specialties and all geographic areas should have a meaningful opportunity to choose the APM pathway by having PFPMs available to them.

a. Definition of Physician-focused Payment Models

How should "physician-focused payment model" be defined?

The definition should be as broad as possible. As long as a model uses a payment method other than traditional FFS, achieves certain agreed-upon quality metrics and reduces spending, it should be considered a candidate for approval. CMS should ask what costs the model

participants are likely to incur in order to participate in the model, what savings the model is likely to achieve for Medicare, what accountability measures should be used to judge whether the model is meeting its targets for costs savings and care quality, and how to hold participants accountable for these measures. A well-designed APM will pay adequately for high-value services and avoid financially penalizing physicians when they reduce avoidable services and prevent complications. Physicians need the flexibility to use payments in various ways in order to improve care and reduce overall spending. A narrow definition will inhibit innovative ideas.

b. Criteria for Physician-Focused Payment Models

What criteria should be used by the Committee for assessing PFPM proposals submitted by stakeholders? We are interested in hearing suggestions related to the criteria discussed in this RFI as well as other criteria.

Many of the questions in this RFI would translate to appropriate criteria against which to evaluate PFPMs. Instead of prospectively defining PFPM entities, the PTAC and CMS should evaluate whether or not the proposed model adequately answers each of these questions.

Are there additional or different criteria that the Committee should use for assessing PFPMs that are specialist models? What criteria would promote development of new specialist models?

Specialty-specific APMs should employ performance metrics that are relevant to that specialty rather than broad measures used in primary care-based models like ACOs and Medical Homes. Given the difficulties current APMs have in engaging specialists, CMS should exercise maximum flexibility in the consideration of specialty-specific PFPMs.

What existing criteria, procedures, or standards are currently used by private or public insurance plans in testing or establishing new payment models? Should any of these criteria be used by the Committee for assessing PFPM proposals? Why or why not?

In general, this should be done according to the model that is being proposed in order to encourage innovation.

c. Required Information on Context of Model Within Delivery System Reform

We are seeking feedback on whether these criteria should be included and, if so, whether they should be modified, and whether other criteria should be considered. We are considering that proposed PFPMs should primarily be focused on the inclusion of participants in their design who have not had the opportunity to participate in another PFPM with CMS because such a model has not been designed to include their specialty.

The models should attempt to solve issues in payment policy regardless of whether CMS is already addressing the problem. It is possible that other stakeholders will have better ideas on how to address those issues.

d. Required Information on Model Design

Should CMS require submission of information in the following areas?

- ***Definition of the target population, how the target population differs from the non-target population and the number of Medicare beneficiaries that would be affected by the model.***
- ***Ways in which the model would impact the quality and efficiency of care for Medicare beneficiaries.***
- ***Whether the model would provide for payment for covered professional services based on quality measures, and if so, whether the measures are comparable to quality measures under the MIPS quality performance category***
- ***Specific proposed quality measures in the model, their prior validation, and how they would further the model's goals, including measures of beneficiary experience of care, quality of life, and functional status that could be used.***
- ***How the model would affect access to care for Medicare and Medicaid beneficiaries.***
- ***How the model will affect disparities among beneficiaries by race, and ethnicity, gender, and beneficiaries with disabilities, and how the applicant intends to monitor changes in disparities during the model implementation.***
- ***Proposed geographical location(s) of the model.***
- ***Scope of EP participants for the model, including information about what specialty or specialties EP participants would fall under the model.***
- ***The number of EPs expected to participate in the model, information about whether or not EP participants for the model have expressed interest in participating and relevant stakeholder support for the model.***
- ***To what extent participants in the model would be required to use certified EHR technology.***
- ***An assessment of financial opportunities for model participants including a business case for their participation.***
- ***Mechanisms for how the model fits into existing Medicare payment systems, or replaces them in part or in whole and would interact with or complement existing APMs.***
- ***What payment mechanisms would be used in the model, such as incentive payments, performance-based payments, shared savings, or other forms of payment.***
- ***Whether the model would include financial risk for monetary losses for participants in excess of a minimal amount and the type and amount of financial performance risk assumed by model participants.***
- ***Method for attributing beneficiaries to participants.***
- ***Estimated percentage of Medicare spending impacted by the model and expected amount of any new Medicare/Medicaid payments to model participants.***
- ***Mechanism and amount of anticipated savings to Medicare and Medicaid from the model, and any incentive payments, performance-based payments, shared savings, or other payments made from Medicare to model participants.***

- ***Information about any similar models used by private payers, and how the current proposal is similar to or different from private models and whether and how the model could include additional payers other than Medicare, including Medicaid.***
- ***Whether the model engages payers other than Medicare, including Medicaid and/or private payers. If not, why not? If so, what proportion of the model's beneficiaries is covered by Medicare as compared to other payers?***
- ***Potential approaches for CMS to evaluate the proposed model (study design, comparison groups, and key outcome measures).***
- ***Opportunities for potential model expansion if successful.***

We agree that it would be beneficial for CMS to recommend PFPM proposals use these items as a guide, but requiring all of them in an application may be unnecessarily burdensome. The PTAC should be afforded leeway to consider these criteria as appropriate.

C. Technical Assistance to Small Practices and Practices in Health Professional Shortage Areas

For section 1848(q)(11) of the Act—What should CMS consider when organizing a program of technical assistance to support clinical practices as they prepare for effective participation in the MIPS and APMs?

Technical assistance should prioritize smaller, independent practices that will be much less able to bear the administrative burden of the significant reporting requirements and the potential financial burden of participating in APMs.

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

Sincerely,

Mark S. Allen, MD
President