

The Society of Thoracic Surgeons

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Eric Gilbertson CMS MACRA Team Health Services Advisory Group, Inc. 3133 East Camelback Road, Suite 240 Phoenix, AZ 85016-4545

RE: Draft Quality Measure Development Plan

Dear Mr. Gilbertson:

On behalf of The Society of Thoracic Surgeons (STS), thank you for the opportunity to provide comments on the draft quality Measure Development Plan (MDP). 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.

STS appreciates the opportunity to comment on ways to develop quality measures that will support current (and future) quality improvement and payment reform efforts. Our comments below address a number of the topics on which the Centers for Medicare & Medicaid Services (CMS) has requested feedback.

Quality Measure Development Funds

The STS National Database was established in 1989 as an initiative for quality assessment, improvement, and patient safety. The Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. About 95% of the adult cardiac surgical procedures performed in the United States are captured in the Adult Cardiac component. The fundamental principle underlying the STS National Database initiative is that surgeon engagement in the process of collecting detailed clinical information on every case, robust risk-adjusted outcomes assessment based on pooled national data, and feedback of these risk-adjusted results to individual practices and institutions, will provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients. In fact, published studies indicate that the quality of care has improved substantially as a result of efforts directly related to the STS National Database.

In addition, STS believes that the public has a right to know the quality of surgical outcomes and considers public reporting an ethical responsibility of

the specialty. Therefore, STS Public Reporting Online enables STS Adult Cardiac and Congenital Heart Surgery Database participants to voluntarily report to each other and the public their heart surgery scores and outcomes. While the patient and caregiver experience data are not presently collected, we are already sharing vital information on surgical outcomes.

As you are aware, the Medicare Access and CHIP Reauthorization Act (MACRA) requires the Secretary of Health and Human Services to award grants to facilitate quality measure development and improvement between fiscal years 2015 and 2019. We believe that Congress intended to allocate funds to bolster quality improvement efforts already underway as well as stimulate innovation in areas of medicine that may not have substantive quality measurement infrastructure already in place.

The success of the Merit-based Incentive Payment System (MIPS) is contingent upon all physician specialties having a sufficient set of actionable and relevant measures that improve patient care and allow physicians to comply with the program. Physician-led organizations are best suited to develop new measures that are useful to their members, harmonize with clinical data registry activities, complement specialty developed alternative payment models (APMs), and fulfill their long-term goals of improving patient care and the practice of medicine. The majority of STS quality measures are submitted to the National Quality Forum (NQF) for endorsement, an extremely rigorous process conducted by technical experts and multi-stakeholder committees. The Society has the most NQF-endorsed performance measures of any other professional society (34 as of January 2016).

STS and other organizations that have pioneered quality measurement and quality improvement initiatives will serve a critical role in supporting the new payment paradigm. We believe that the funding should be used to support these ongoing efforts in addition to stimulating quality measure development in segments of medicine that do not currently have a wealth of quality measures. Finally, these authorized funds should be used to help streamline electronic capture of clinical registry data to help facilitate real-time quality measurement and analysis.

We urge CMS to promptly release the MACRA-authorized funds for these purposes.

General Comments

We believe collecting and reporting quality data is the most powerful mechanism to change and improving the practice of cardiothoracic surgery for the benefit of patients. We also firmly believe that the reporting burden placed on physicians should be minimized as much as possible. Current CMS quality reporting options like the Qualified Clinical Data Registry (QCDR) program allow physicians to use the data that they already report to a registry to comply with CMS reporting requirements. In many ways, this is the best of both worlds, as we believe that the STS National Database, currently a QCDR, is a superior tool for quality measurement and improvement. We urge CMS to retain the QCDR reporting option in the new MIPS paradigm. Further, we hope that CMS will work with QCDRs to ensure that any additional quality reporting requirements are incorporated into the QCDR program so physicians can still use only one mechanism for quality reporting.

That said, CMS highlighted patient input, care coordination, and appropriate use as possible focal points for new measures. Not every registry currently collects – nor is designed to collect – these types of information. In order to overcome major hurdles, mature procedure-based registries like the STS National Database would need to re-engineer their data elements and infrastructure. Such substantial changes will require a significant investment of resources, and a reasonable amount of time to phase in any adjustments would be necessary.

Technical Principles

CMS proposes to include measure stratification across different patient demographic characteristics. While potentially useful, this recommendation may not be easily implemented. The STS National Database collects information on race only if it is voluntarily reported. We are not able to collect all of the demographic information outlined in the draft MDP, nor can it be mandatory to report protected health information (PHI) given the privacy limitations of the Health Insurance Portability and Accountability Act.

Measure Integration to Support MIPS and APMs

The draft MDP states the development of new measures funded under MACRA will begin to address gaps in the measure portfolio, and that resulting measures will, among other things, use data generated from electronic health records (EHRs) and produce results that are stratified by race, ethnicity, gender and other available demographic variables.

EHRs have not yet achieved interoperability among the various systems and there is very little exchange currently between EHRs and clinical registries. A clinical data registry, like the STS National Database, has highly structured, standardized data definitions and strict control over the accuracy and integrity of the data. On the other hand, EHR data are primarily unstructured and lack specific data definitions or controls over who enters the data. The data sets are very different, and while it is possible to link some data elements between EHRs and clinical registries, for many other data elements it is currently impossible to reasonably populate a complex clinical data registry like the STS National Database with EHR-reported data. Linking EHR to clinical data registries will require cooperation from EHR vendors and testing to ensure data accuracy.

The STS National Database software vendors can currently pull basic demographic information from EHRs (e.g., name, admission date, and discharge date). However, we do not recommend the collection of additional information from EHRs before harmonization across data sources is established and the quality of the data can be verified. Additionally, as mentioned earlier, demographic data that are considered PHI are protected and cannot be mandated for collection.

Clinical Care

CMS plans to develop measures for the clinical care domain including patient-reported outcomes measures. While STS recognizes the importance of patient-reported outcomes, the STS National

Database does not yet collect this type of information. However, we are exploring ways to collect this information without creating additional burden for providers.

Per above, we urge CMS not to impose multiple reporting requirements on participating physicians. We would also like to work with CMS and patient advocacy organizations to develop tools that could adequately and accurately depict the patient experience while not subjecting physicians to negative and subjective assessments of their performance that reflect variables outside of their control.

Care Coordination

CMS intends to incorporate both primary care and specialist accountability across care settings. The draft MDP also states the ability to link disparate data sources is critical to the development of innovative care coordination quality measures. STS would like greater clarification on how CMS plans to attribute care across providers.

Population Health

CMS is considering the development of outcomes measures at a population level to assess the effectiveness of the health promotion and preventative services delivered by professionals. STS members are specialists who generally do not engage in preventive care beyond providing general smoking cessation resources to patients. Measures in this domain would be ideally developed for eligible professionals that regularly offer preventive care and wellness services. We also urge CMS to exercise careful consideration if outcome measures for a population of patients are to be applied to specialty physicians.

Gap Analysis

CMS plans to focus on the development of measures in areas where insufficient quality measures exist. In general, STS supports the proposal to leverage the Measure Applications Partnership and its processes for gathering input from stakeholders in the selection of measures to be adopted. In addition, we encourage CMS to solicit input directly from the individual specialties. For example, STS can refer to data from the STS National Database to determine where gaps exist, and share the information with CMS for the purpose of measure development.

Consideration for Electronic Specifications

CMS intends to prioritize electronic clinical quality measure development. STS encourages CMS to wait for electronic platforms to be harmonized before attempting to develop measures for electronic specification.

Access to Medicare and Other Payor Claims Data

In addition to quality measure development, MACRA requires CMS to begin to evaluate resource use and efficiency across all of medicine. This principle is also captured in the proposed

MDP. Also included in MACRA was a requirement that CMS begin to share Medicare claims data to QCDRs "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.¹" Unfortunately, CMS has recently published a proposed regulation ([CMS-5061-P] – Medicare Program: Expanding Uses of Medicare Data by Qualified Entities) wherein CMS states that its obligation under the statute is already fulfilled. STS will be providing comments on this regulation in the future. However, we wish to highlight here, the role that seamless integration of clinical and claims data would play in pursuit of CMS's goal to measure resource use and efficiency of care under this proposal. If the STS National Database were to have continuous access to Medicare claims data, not access predicated on a request for a specific research purpose, we would be able to assess the longitudinal efficacy of the surgical interventions captured in the database.

Thank you for the opportunity to share our thoughts on the draft MDP to ensure the Medicare program and U.S. health care system can successfully transition to rewarding quality, rather than volume, of care. If you have any additional questions, please contact Courtney Yohe, Director of STS Government Relations at 202-787-1222, or by e-mail cyohe@sts.org.

Sincerely,

Joseph E. Bavaria, MD President

¹ P.L. 114-10, Sec 105(b)