



The Society of Thoracic Surgeons

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July 7, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health & Human Services
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: CMS-9928-NC; Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients

Dear Administrator Verma,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments regarding the request for information titled "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care & Improving Healthcare Choices to Empower Patients" as published in the *Federal Register* on June 12, 2017. We appreciate the opportunity to provide comments on minimizing the regulatory burdens that interfere with the physician-patient relationship.

Founded in 1964, STS is an international not-for-profit organization representing more than 7,200 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 this Administration's efforts to recognize and alleviate regulatory burdens that hinder the physician's ability to care for their patients. We hope you will consider addressing the following:

Provide a pathway by which specialty-specific quality measures can be used in the Quality Payment Program (QPP)

The Medicare Access and CHIP Reauthorization Act (MACRA) was designed to promote value (quality / cost) rather than simply rewarding physicians for the volume of service they provide. This means CMS must be able to effectively measure quality. STS has been a pioneer in this space with 34 quality measures endorsed by the National Quality Forum (NQF), second only to CMS in number of NQF-endorsed quality measures.

However, it has come to our attention that many employed surgeons will be included under their hospitals' tax identification numbers for purposes of quality reporting under the Quality Payment Program (QPP). This arrangement will mean that cardiothoracic surgeons will not have the ability to influence their own personal

quality scores as the hospitals may elect to report on quality measures that are insignificant or irrelevant to cardiothoracic surgery. This will result in a number of problems for physicians, patients, and the Medicare program:

- a. MACRA was founded on the principles of promoting and incentivizing quality care throughout health care. However, without utilizing cardiothoracic surgery specific quality measures, CMS will fail to incentivize quality in one of the specialties that has the largest impact on Medicare beneficiaries and is one of the largest cost centers in the Medicare program.
- b. Without utilizing measures specific to cardiothoracic surgery, cardiothoracic surgeons will not be able to quantify their value to their employers and will have their contribution to the overall performance of the hospital diminished.

STS urges CMS to ensure that specialists, including employed physicians, have the option to report on quality metrics that are germane to their practice. Allowing specialty-reporting options will provide CMS and hospitals/ health systems better understanding of physicians' contributions to increasing value in healthcare.

Ensure appropriate implementation of data collection requirements for global surgical payments

Section 523 of MACRA prohibited CMS from implementing changes to global payments for surgical services without first collecting data on the number and level of visits being performed in the post-operative period. This provision was included in MACRA in response to an effort by CMS to require that a surgeon bill separately for each service performed in the post-operative period.

Data collection efforts, which include mandatory reporting of a single code (99024) for every post-operative visit performed by surgeons in nine states and a broader survey of surgeons across the United States began July 1. STS remains concerned that without the time needed to effectively educate providers on the data collection and without CMS's communication regarding logistics, submission, and analysis of the data, we fear that CMS will not accurately capture the data needed for a comprehensive view of postoperative care. Without an accurate picture of postoperative care, we fear the valuation of these procedures starting in 2019 may be flawed. While we support CMS's efforts to promote quality care and gain a better understanding of postoperative care in the clinical setting, we believe there is still considerable confusion in the surgical community about how to correctly provide the required information to CMS. These concerns include questions on the definition of "practitioners" and "groups," submission of claims for patients seen twice in one day, and CMS's analysis of the data.

We encourage CMS to provide more education to providers on this data collection effort to ensure a more complete picture of the postoperative services of cardiothoracic surgeons. Further, we ask that CMS halt implementation of data collection until the data collection methodology can be validated.

Provide qualified clinical data registries (QCDRs) with continuous access to Medicare claims data

Section 105(b) of MACRA requires CMS to provide QCDRs with access to Medicare claims data "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically

valid analyses and research **to support quality improvement or patient safety.**” (Emphasis added.) The statutory language suggests that QCDRs must have broad and continuous access to large Medicare claims database, such as the 100% Medicare inpatient claims file, in order to conduct the probabilistic matching and linking process to facilitate these analyses. In its drafting of this section of MACRA, Congress intended that, by virtue of meeting the requirements to become a QCDR, registries would automatically be eligible for access to Medicare data for linking purposes. At present, QCDRs are still unable to access Medicare claims data for these purposes.

The STS National Database (the Database), currently approved by the CMS as a Qualified Clinical Data Registry (QCDR), was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. The fundamental principle underlying the STS National Database initiative has been that surgeon engagement in the process of collecting information on every case combined with robust risk adjustment based on pooled national data, and feedback of the risk-adjusted data provided to the individual practice and the institution, 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 as a result of research and feedback from the STS National Database.

The Database has facilitated advancements in many aspects of health care policy including public reporting of health care quality measures, facilitating medical technology approval and coverage decisions, and even saving money by helping cardiothoracic surgeons to find the most efficient and effective way to treat patients. Clinical data from the STS National Database has been linked with administrative claims data from CMS on a number of occasions either as a part of a specific research request to the Research Data Assistance Center (ResDAC) or through our data warehouse at the Duke Clinical Research Institute (DCRI). These discrete instances have demonstrated important new ways to assess the effectiveness of treatment options and offered new avenues for medical research. Clinical data yield sophisticated risk-adjustment assessments, while administrative data provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs.

Given STS’s long history as a reputable QCDR, we were optimistic about the opportunity to access Medicare claims data. Sadly, CMS has not implemented Section 105(b) to align with the Congressional intent. Rather than establishing a process that would allow QCDRs to begin data linkage through *continuous* access to Medicare claims data, CMS proposed that QCDRs utilize the existing process within ResDAC to seek claims data for *specific* research projects. This proposal was not aligned with the statutory language provided in Section 105(b) of MACRA. A second proposal from CMS offered a “quasi-qualified entity program” as an option for QCDR access to claims data. This method was also not in keeping with statutory intent.

STS remains steadfast in our belief that providing QCDRs such as the STS National Database with access to Medicare claims data is essential to help us to better understand and promote value and quality within our healthcare system. Fortunately, STS has had promising discussions with CMS regarding implementation of Section 105b and improved workflow within ResDAC. We look forward to working with CMS on bringing these implementation ideas to fruition.

Make changes to the Coronary Artery Bypass Graft (CABG) Episode Payment Model (EPM) so CMS can benefit from stakeholder efforts and resources intended to improve patient care

We regret that the proposed CABG EPM was developed largely without any stakeholder feedback and was implemented as a mandatory bundled payment program. STS had been working on many innovative ideas that would promote value in the field of cardiothoracic surgery and would have appreciated the opportunity to partner with the Center for Medicare and Medicaid Innovation (CMMI) early in the process. Instead, the CABG EPM was proposed as a mandatory program that was developed without feedback from stakeholders and many of our innovative suggestions presented during the comment period were not able to be implemented because they would have required a new rulemaking.

The CABG EPM is predicated on the notion that bundles will facilitate care coordination and better-coordinated care will improve quality and reduce cost. STS believes there is a more direct way to influence quality and reduce cost. By combining the clinical information in the STS National Database with claims data (per above) we can facilitate quality improvements that will generate savings in ways that the currently proposed models cannot. Establishing a linkage would allow CMS to target the major cost center in the CABG bundle: the index admission rather than hoping to squeeze most of the EPM savings out of the 20% of the cost that is accrued after discharge. Claims data, when combined with clinical information will provide STS members with information on long term outcomes, costs, readmissions, and re-interventions. A blended database could be used to develop best practice protocols aimed at reducing health care costs by minimizing complications and/or cutting excess resource utilization while maintaining quality.

The CABG EPM proposal includes two required quality measures: all-cause mortality and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. While we appreciate that, in the final rule, CMS allowed surgeons participating in the CABG bundle to opt to use the STS CABG composite score rather than all-cause mortality, we question how CMS intends to distinguish among the various participants in the model who do not use the CABG composite. All-cause mortality, for CABG is already below 2% making it very hard to distinguish among the program participants who meet the required metric. This is a prime example of why CMS needs stakeholder engagement early on and throughout the APM development process.

In addition, we maintain that the “discounts” applied to hospitals in the CABG EPM must be decreased. Surgeons (via their hospitals) will be the ones responsible for success under the proposed model but they have minimal influence in the post-acute setting where the majority of the savings are expected to take place. This may cause surgeons to avoid high risk cases. The risk methodology for payment should rely on clinical data and the STS Risk Calculator (already utilized by CMS in other settings) rather than claims data. Hospitals need to have more control over where the patient goes after discharge. While patient choice and comfort should always be protected, the surgeon/hospital should not be held accountable if the patient chooses a sub-optimal post-discharge facility.

STS strongly urges CMS to reassess the current CABG EPM and seek stakeholder buy-in before implementing any new, mandatory payment models.

Make it easier for physician-focused alternative payment models (APMs) to be implemented

MACRA was founded on the principles of incentivizing value over volume. As such, considerable emphasis was placed within MACRA on development of and participation in alternative payment models (APMs). Specifically, Congress created the physician-focused payment model technical advisory committee (PTAC) to both improve transparency at Center for Medicare and Medicaid Innovation (CMMI) and increase the variety, efficacy and number of APMs, in hopes of maximizing the number of physicians and medical specialties able to participate.

STS was prepared to offer a physician focused payment model (PFPM) to both the PTAC and the Center for Medicare and Medicaid Innovation (CMMI) for consideration and implementation. Because of our unique resource – the STS National Database – we believed that we would be able to demonstrate to the Centers for Medicare and Medicaid Services (CMS) a payment model capable of rewarding physicians for increasing the quality of care they provide and reducing resource use. Unfortunately, the APM pathway has become extremely complicated and difficult to navigate. The Society supports policies and activities that enhance the abilities of our surgeons to deliver the highest quality and most cost efficient value based care to our patients. We hope physician-focused payment models will be an opportunity to demonstrate and codify that commitment. Congress created the PTAC to both improve transparency at CMMI and increase the variety, efficacy and number of APMs, in hopes of maximizing the number of physicians and medical specialties able to participate. We believe that we are uniquely situated to demonstrate how the Medicare program might accurately reimburse cardiothoracic surgeons for improved health care quality and patient outcomes.

The Society urges CMS to prioritize stakeholder participation in the development of Advanced APMs that are relevant to specialty medicine and allow for a streamlined process within an achievable timeframe.

Conclusion

The Society strongly believes that streamlining the above regulatory burdens will allow our members to provide a greater level of quality and efficient care and will ensure a strong physician-patient relationship. Moreover, addressing the regulatory burdens and allowing increased access to Medicare claims data will allow STS to link outcomes and cost data to better understand value in our healthcare system. We would welcome the opportunity to be a resource to CMS as continued discussions on the effects of regulatory burdens is considered. Please contact Courtney Yohe, MPP, Director of Government Relations at cyohe@sts.org or 202-787-1230 for questions or clarification.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Prager". The signature is fluid and cursive, with a large initial "R" and "P".

Richard Prager, MD
President