May 31, 2013

Honorable Max Baucus
Chairman
Committee on Finance
United States Senate
Washington, D.C. 20510

Honorable Orrin Hatch
Ranking Member
Committee on Finance
United States Senate
Washington, D.C. 20510

Dear Chairman Baucus and Ranking Member Hatch:

On behalf of The Society of Thoracic Surgeons (STS), the largest organization representing cardiothoracic surgeons in the United States and the world, I write to provide comments in response to your May 10, 2013 letter to the Health Care Provider Community pertaining to Medicare Physician Payment Reform. Founded in 1964, STS is an international, not-for-profit organization representing more than 6,600 surgeons, researchers, and allied health care professionals in 85 countries who are dedicated to providing patient-centered high quality care to patients with chest and cardiovascular diseases, including heart, lung, esophagus, transplantation, and critical care. 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.

With the recent publication of the Congressional Budget Office’s Budget and Economic projections for 2014-2023, it is clear that Congress must act now while the cost of SGR repeal is significantly lower. Although expected growth in Medicare spending has slowed, there is no guarantee that the trend will continue. Congress has the opportunity to take SGR off the books at a significantly reduced cost and we cannot afford to let this opportunity slip by. We urge Congress to act and support the current effort by the committees to draft legislation for that purpose that recognizes and attempts to leverage the power of clinical registries. We appreciate the Committee’s commitment to this effort and offer our response to the questions posed by the Committee below.

Background

The STS National Database was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The STS National Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. The STS Adult Cardiac Surgery Database is the world’s premier clinical registry for cardiac surgery. The fundamental principle underlying the STS database initiative has been that engagement in the process of collecting information on every case, robust risk-adjustment based on pooled national data, and feedback of this risk-adjusted data to the individual practice and institution will provide the most
powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients and the public. Published studies indicate that the quality of care is improving. We wish to point out an example of the power of the STS database effort. ElBardissi and colleagues studied 1,497,254 patients who underwent isolated primary Coronary Artery Bypass Graft (CABG) at The Society of Thoracic Surgeons participating institutions from 2000 to 2009. They found that:

- Patients in 2009 had more preoperative diseases: compared with the year 2000, patients undergoing isolated primary CABG in 2009 were more likely to have diabetes mellitus (40% vs. 33%) and hypertension (85% vs. 71%).
- Patients received more indicated care processes in recent years, including a 7.8% increase in the use of angiotension-converting enzyme inhibitors preoperatively and a significant increase in the use of the internal thoracic artery (95% in 2009 vs. 88% in 2000).
- Although predicted mortality rates of 2.3% were consistent between 2000 and 2009, the observed mortality rate over this period declined from 2.4% in 2000 to 1.9% in 2009 representing a relative risk reduction of 24.4%.
- The incidence of postoperative stroke decreased significantly from 1.6% to 1.2%, representing a risk reduction of 26.4%.
- There was also a 9.2% relative reduction in the risk of reoperation for bleeding and a 32.9% relative risk reduction in the incidence of sternal wound infection.

In general, we agree with the Committee’s notion that, while the current fee for service (FFS) payment system should eventually be replaced, the health care system will not sustain a wholesale change at this time. STS, through our collaborations with other specialties, has developed the innovative multidisciplinary “heart team” concept that has implications across our segment of health care. For example, using the heart team model, we have helped to facilitate the approval and eventual coverage of new medical technology. Data collection around each step of the introduction of such technology yields itself to real time comparative effectiveness research with robust clinical and demographic information. We believe that heart team collaborations lead to the best possible care for our patients. We look forward to working with the committee to develop an eventual payment model that values this type of care coordination and reimburses surgeons, physicians, and other health care professionals for the essential skills they bring to each step of this collaboration.

STS remains hopeful that other Medicare initiatives, such as the Value Based Modifier (VBM), that attempt to improve, and even to pay for improved quality care, would be supplanted by the reformed fee for service (FFS) system referred to in this letter. Implementing a VBM, or a similar program, concurrently with the reformed FFS would be confusing and, potentially counterproductive. In addition, we hope the committee will continue to monitor the implementation of current alternative payment models, including Accountable Care Organizations (ACO) and others that might blur the lines between Medicare Parts A and B. In the ACO and other payment models, it remains to be seen who will receive the incentive payment for improved quality and/or reduced cost, and how that check will be divided among the
providers. As STS represents surgical specialists who predominantly perform their services in a hospital setting, we remain skeptical, yet vigilant, to ensure that the process is equitable.

Questions

MedPAC and others have suggested changes they believe would improve the accuracy of fee schedule payment amounts and the validity of resource input used to establish payment for services under the fee schedule. What specific reforms should be made to the physician fee schedule to ensure that physician services are valued appropriately?

Congress should encourage CMS to use real, clinical data on procedural time and hospital lengths of stay collected via a clinical registry rather than time estimates which distort the relativity of the fee schedule. STS has used the time data from the STS National Database as the basis for relative value recommendations to the AMA Relative Value Update Committee.

Unfortunately, the use of this type of real data has been resisted by CMS with the rationale that other specialties are not able to provide comparable data. Clearly, such a change would require that the requisite clinical registry infrastructure be in place. However, we believe that this change in the Resource-Based Relative Value System (RBRVS) is a tremendous incentive for specialties to invest in such an infrastructure.

The essential impact of the SGR has been to hold physician payment constant while Medicare’s purchasing power for physicians’ services has been eroded by general inflation and further reduced by the need to subsidize the static practice expense payment component in the face of medical cost inflation. This impact has reached the crisis point for family practice and other primary care specialties that have not been able to increase their volume of services or otherwise gain efficiencies for a variety of reasons.

In turn, the system used to determine physician work (the RUC) has been influenced by external forces requiring that a transfer within the SGR to primary care specialties from procedural specialties be made. Within the constraints of RBRVS and the SGR, the only method to accomplish this is to increase the intensity and complexity measures of cognitive work in the face of decades of established relativity to the contrary. Thus, the calls for “representativeness” at the RUC are simply calls to force redistribution of physician payment into a form of equality for all types of physician work regardless of its intensity and complexity.

Absent the SGR, the conversion factor would have increased substantially during this time period and the economic realities suffered by primary care physicians would not now exist. Further, absent the SGR, the country would have directly faced the need to control the volume of all services, and perhaps especially procedural service, by assessing their value to patients rather than to physicians. In this regard, all procedural services are not alike. Many have extremely robust evidence bases indicating that patient survival is enhanced by a procedure.

The committee should be aware that CMS, in attempting to transfer funding from procedural services to primary care and cognitive services, is currently considering an arbitrary reduction in its allocated time for physician payment for coronary bypass surgery. This reduction would be directly contradicted by STS National Adult Cardiac Database registry data that indicates that the
time required to provide this service has actually increased due to changes in the patient population. If this action occurs, it will only further detract from the relativity of the physician fee schedule and remove one of the few links that it has to objectively measurable elements of physician work.

Our inability to directly address this issue is the root cause of excess health care expenditure, and can only be resolved by direct measures at the service level to ensure that medical necessity exists and can be met for the individual patient. Attempts to reduce payment for services perceived to have lesser value will only increase the volume of these services as physicians behave as individuals rather than as societally responsive groups.

For these purposes, and other valuable public health initiatives, Congress must ensure that administrative claims (resource utilization) data be made available for linkage to clinical registries such as the STS database. The ability to link clinical data with administrative data has opened up 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. STS has successfully linked its clinical data with CMS MEDPAR information, on a project-by-project basis, to obtain longitudinal outcomes data for a wide array of cardiothoracic surgery operations. Linked data are particularly useful in conducting comparative effectiveness research (CER) and establishing appropriateness of care.

In addition, linking clinical registries to the Social Security Death Master File (SSDMF) allows for the verification of ‘life status’ of patients who otherwise would be lost for follow up after their treatment. The outcomes information derived from these data sources helps physicians to provide information to today’s patients and families to help them with shared decision making. Valid and reliable outcomes data give patients confidence in their medical interventions and demonstrate to patients and their families the durability and long-term benefits of medical procedures. It is important to note that STS, through its contracts with the Duke Clinical Research Institute, maintains the patient identifier data separately from the actual clinical and other demographic data, and the only patient level identified information that ever leaves the database is simply that the patient has a record in the database. When the follow-up information is returned from external entities, such as the SSDMF, it is linked back to the records in the de-identified database, but the flow of information is only in this direction. The externally derived data are used to supplement the data in the individual record, but these clinical, patient level data never leave the database except in de-identified form.

Unfortunately, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the SSDMF. There are continuing efforts to further restrict access to the SSDMF so as to protect those listed in the file from identity theft. Balanced against these legitimate privacy concerns are the many advantages of SSDMF data.

Importantly, STS believes that meaningful quality measures and rewards for physician performance cannot be applied simply to administrative data reported by hospitals and physicians alone. While administrative data provide information on longitudinal medical
treatment and resource utilization across settings of care and by various physicians, their clinical accuracy have been shown to be poor, and they exclude pertinent information on patient risk factors, disease severity, and clinical outcomes. This critical information is only found in clinical datasets where there is input of clinical data by clinicians.

*Physician Services are critical to the ongoing health of Medicare Beneficiaries. Appropriate utilization of physician services can lessen disease burden and reduce avoidable emergency department visits and hospitalizations. However, inappropriate or excessive utilization of physician-related services can negatively impact beneficiary health and drive up Medicare spending. Volume control mechanisms are not an inherent component of a FFS system. The SGR was intended to address excessive volume, but its mechanism is fatally flawed. What specific policies should be implemented that could coexist with the current FFS physician payment system and would identify and reduce unnecessary utilization to improve health and reduce Medicare spending.*

STS agrees that the SGR model has failed to control the volume of services. We believe that the collection of data on every patient, central risk adjustment, and feedback of risk-adjusted outcomes information to the practice and practitioner level is the most reliable mechanism to affect changes in practice. The linkage of clinical and administrative claims data (as outlined above) can provide longitudinal outcome information on both clinical outcomes and resource utilization which will, in turn, allow the assessment of the value of the clinical care that has been delivered. Since survival and resource utilization information is such an important part of the outcomes for cardiothoracic surgery quality improvement efforts, we urge that steps be taken to insure these registries have access to claims data from CMS (and, hopefully, other payors) and outcomes (death) data from the Social Security Administration or another, accessible source. It is imperative that any physician payment legislation address this foundational issue.

Unfortunately, for many physicians, procedure volume and professional liability are inextricably connected. STS believes that setting standards aligned with best practices identified by specialty societies that are equipped with relevant, clinical data and risk adjusted outcomes information is the best way to institute meaningful medical liability reform. The Society of Thoracic Surgeons Workforce on Evidence Based Surgery has developed evidence-based guidelines to provide practical assistance to STS membership. Thorough research of each guideline topic is completed through an exhaustive review of clinical information. The conclusions and recommendations are based on a review of scientific evidence published in the medical literature. STS Clinical Practice Guidelines are intended to assist physicians and other health care providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. In addition, 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. This information, when used in the context of multi-stakeholder collaboration, provides additional layers of patient protection.

Quality measurement and data on clinical risk can be used to reduce lawsuits and the cost of liability insurance, and to restore balance to the justice system. However, tort-reform should not
be implemented in a way that is overly burdensome on specialty societies in general. To that end, we realize that there is a right way and a wrong way to utilize clinical guidelines. Guidelines must be specific to ensure that poor clinical practices or judgments that meet minimum standards are not considered as justifiable, but guidelines cannot replace clinical judgment and experience. Practice guidelines should protect physicians who are following them, but guidelines should not be able to be construed in a way that would make a physician vulnerable for a malpractice suit because he/she has exercised clinical judgment on an individual case and departed from the published “standards.” A talented clinician is not one who blindly adheres to established guidelines but rather one who recognizes that patient care must be individualized, occasionally requiring deviation from guidelines that are effective in the overwhelming majority of patients.

Shifting from a FFS system to an alternative payment model will be a major change for many physicians. Within the context of the current FFS system, how specifically can Medicare most effectively incentivize practices to undertake the structural, behavioral, and other changes necessary to participate in alternative payment models?

Per above, changes to the RVRBS to rely on real clinical information rather than survey information would push all medical specialties to develop clinical registry infrastructure. However, STS also believes that physicians can and should be rewarded for the provision of efficient, quality health care. Cardiothoracic surgical examples of these structures include not only the STS National Database efforts, but also state and regional efforts such as the Virginia Cardiac Surgical Quality Initiative (VCSQI), the Michigan-STS collaboration on adult cardiac surgery, and the Northern New England Cardiovascular Study Group, among others.

VCSQI was formed in 1994, with the express purpose of improving clinical quality across an entire state in cardiac surgical programs of all sizes through data sharing, outcomes analysis, and process improvements. It is founded on the principle that a focus on quality will contain costs by lowering complications, improving efficiency, and reducing resource utilization.

All of the VCSQI programs participate in the STS National Database and uniformly follow the definitions and measures in this landmark clinical registry. This regional quality initiative has constructed a database of over 80,000 patients who have undergone cardiac surgical procedures. The database is unique in that it matches the patient’s clinical outcome data with each patient’s discharge financial data. Each record includes clinical outcome tied to costs for each episode of care. On a quarterly basis, each program’s clinical and financial outcomes are reviewed and used to develop new evidenced-based methodologies to improve care in cardiac surgery. VCSQI has served as a test bed for the STS’s evidenced-based guidelines to be implemented.

VCSQI has attempted to test a global pricing model and has implemented a pay-for-performance program where physicians and hospitals are aligned with common objectives. Although this collaborative approach is a work in progress, collaborators point out that a road map of short-term next steps is needed to create an adaptive payment system tied to the national agenda for reforming the delivery system.
STS believes that placing incentives at a higher level (practice or even regional as per above) can encourage collaborative learning and quality improvement that should be inherent aspects of professionalism and can avoid incentives to “game the system” or to refrain from sharing knowledge and clinical experience. Placing the focus on the individual practitioner detracts from the heart team approach to patient care that has become the hallmark of the advances in our specialty of late. In order for the heart team to function at its highest level, there must be shared responsibility for patient care and patient outcomes. Assessing care quality at the institutional, regional, or national level allows the component parts of the heart team to share accountability, ensuring the patient receives the best care from the appropriate health care provider.

Although some specialties have not yet established their own quality measures, STS believes that all physicians should be working to improve patient outcomes through quality assessment. A new payment model could be designed to accommodate such specialties while they develop the databases and registries that should serve as the basis for credible and statistically valid measures necessary to fulfill the promise of this policy. We would encourage policy-makers not to delay implementation of payment reform for those who are able to fulfill many of these requirements today.

Conclusion

We believe that an outcomes-based/data driven approach to care should be encouraged and supported, and that specialty societies are the best entities capable of generating relevant and clinically meaningful measures that are widely accepted by all stakeholders, including providers, patients and third party payers. The ideal source for such data are clinical registries designed by content experts—the physicians and surgeons in a particular specialty. Sufficiently granular information should be collected to ensure robust risk-adjustment so that practices and hospitals caring for sicker patients are not penalized. Similarly, specialties will determine the most appropriate outcomes to measure, in most instances focusing on objective outcomes measures such as death and complications. A mechanism such as the STS National Database 1) takes advantage of an existing, nationally standardized, and validated data infrastructure, 2) minimizes duplication of quality reporting mechanisms, and 3) provides a method for reporting transparency among providers. It is, however, essential that any specialty-specific database be carefully audited by an external entity to maintain the integrity of the database and the process of quality improvement. In the case of STS, we contract with Telligen to randomly audit 8% of all STS participant programs annually, and we intend to increase the percentage of sites audited to 10% next year.

There must be a central review process, such as the process utilized by the National Quality Forum (NQF), to ensure the measures chosen by each specialty are valid and meaningful. The AMA Relative Value Update Committee and Physician Consortium for Performance Improvement are also examples of entities that utilize processes that are transparent and evidence-based.
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Thank you for the opportunity to provide comments during this phase in your process. We appreciate the work the committees have undertaken to help resolve this important issue. If you need additional information, or if STS can be of any assistance, please contact Phil Bongiorno, STS Director of Government Relations, at pbongiorno@sts.org or 202-787-1221.

Sincerely,

[Signature]

Douglas E. Wood, MD  
President