

The Society of Thoracic Surgeons

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March 13, 2015

The Honorable Gene L. Dodaro
Comptroller General of the United States
Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Comptroller General Dodaro,

On behalf of The Society of Thoracic Surgeons (STS), I am pleased to nominate Jeffrey B. Rich, MD to the Medicare Payment Advisory Commission (MedPAC). As a cardiothoracic surgeon, Director of the Virginia Cardiac Surgery Quality Initiative (VCSQI), and Past President of STS, Dr. Rich has demonstrated a profound dedication to advancing the practice of medicine. He is an exceptional candidate for MedPAC because of his unique expertise in Medicare payment and quality improvement policy as a former Director of the Center for Medicare Management and as a former member of the Board of Directors for the National Quality Forum (NQF).

Founded in 1964, STS is an international not-for-profit organization representing more than 6,900 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.

Dr. Rich's leadership roles reflect his extensive knowledge of the U.S. health care system and demonstrate his expertise in both quality improvement and health care economics. As Director of the Center for Medicare Management, he oversaw the regulation and payment of Medicare fee-for-service providers, privately administered Medicare health plans, and the Medicare prescription drug program. At NQF, he served as Chair of the Council on Research and Quality Improvement, where members are engaged in the everyday measurement, evaluation, and research of quality in health care.

During Dr. Rich's tenure as STS President, he oversaw unprecedented collaboration among the Society, the American College of Cardiology (ACC), the Food and Drug Administration, and the Centers for Medicare & Medicaid Services. This effort broke new ground in health policy, pioneering the FDA/CMS parallel review process for a transformative medical device, and launching the groundbreaking STS/ACC Registry™ for transcatheter valve therapy devices.

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Dr. Rich trained at Massachusetts General Hospital, which is the teaching institution for Harvard medical school, transitioned to Stanford University Hospital, and then began his practice in Virginia. It was in Virginia that he applied his robust health care knowledge as a founding member and Director of the VCSQI, a voluntary regional collaborative in the Commonwealth of Virginia that is comprised of 12 cardiac surgical practices in 18 hospitals. The VCSQI is demonstrating that improving quality will reduce costs through the creation of evidence-based protocols using patients' clinical information matched with administrative and cost data. Additionally, Dr. Rich has testified before Congress on numerous occasions, most recently in the summer of 2013, to describe the critical role of the STS National Database and other clinical registries in payment system reform [See Appendix]. Through his work with STS and VSCQI, Dr. Rich has proven that an interdisciplinary, team-based approach to providing the best quality patient care is the most efficacious way to reduce costs and enhance patient outcomes.

In addition to Dr. Rich's commitment to improve health care access and quality, he would fill a void in the panel's medical representation since there are no surgeons on this important Commission. Cardiovascular disease is one of the largest cost centers in the Medicare program, and is the leading cause of death in the United States with a mortality rate of over 375,000 Americans each year.¹ Dr. Rich's clinical experience as a cardiothoracic surgeon with board certification in both general surgery and cardiothoracic surgery, combined with his comprehensive understanding of the health care system, makes him an ideal candidate.

Thank you for considering the STS nomination of Dr. Rich for appointment to MedPAC. Should you have any further questions, please contact Courtney Yohe, Director of STS Government Relations at 202-787-1222 or by e-mail cyohe@sts.org.

Sincerely,



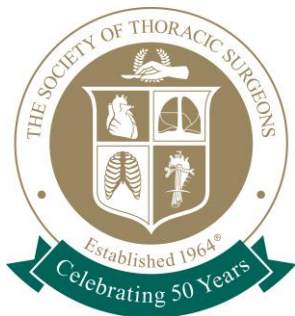
Mark S. Allen, MD
President

¹ Heart Disease and Stroke Statistics – At-a-Glance. (2015, January 1). Retrieved February 27, 2015, from http://www.heart.org/idc/groups/ahamah-public/@wcm/@sop/@smd/documents/downloadable/ucm_470704.pdf

Appendix

House Committee on Energy and Commerce
Subcommittee on Health
Hearing: Reforming SGR: Prioritizing Quality in a Modernized Physician
Payment System
June 5, 2013

Jeffrey B. Rich, MD, Testimony on behalf of
The Society of Thoracic Surgeons



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Chairman Pitts, Ranking Member Pallone, and distinguished members of the Committee, thank you for the opportunity to present my testimony today on behalf of The Society of Thoracic Surgeons. I come to you wearing many hats: Immediate Past President of The Society of Thoracic Surgeons and participant in the STS National Database – one of the longest running, most robust clinical outcomes data registries in existence; former Director of the Center for Medicare Management at the Centers for Medicare and Medicaid Services (CMS); Director at Large of the Virginia Cardiac Surgery Quality Initiative; and a practicing cardiothoracic surgeon at Sentara Heart Hospital and President of Mid-Atlantic Cardiothoracic Surgeons, Ltd. in Norfolk, VA.

The Society of Thoracic Surgeons (STS) is the largest organization representing cardiothoracic surgeons in the United States and the world. 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.

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 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. In fact, published studies indicate that the quality of care has already improved as a result of research and feedback from the STS National Database.

For example, ElBardissi and colleagues studied 1,497,254 patients who underwent isolated primary Coronary Artery Bypass Graft (CABG) surgery at STS National Database-participating institutions from 2000 to 2009. They found that:

- 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 (88% in 2000 vs. 95% in 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% despite the predicted mortality rates (2.3%) remaining consistent between 2000 and 2009.
- The incidence of postoperative stroke decreased significantly from 1.6% to 1.2%, representing a relative 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.

The Virginia Cardiac Surgery Quality Initiative (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 on an ongoing basis. Each record includes clinical outcomes tied to costs for each episode of care. VCSQI has served as a test bed for the STS's evidence-based guidelines to be implemented.

VCSQI has attempted to test a global pricing model and has implemented a pay-for-performance program whereby 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. VCSQI has demonstrated that improving quality reduces cost. For example, using evidence-based guidelines, VCSQI has generated more than \$43 million in savings through blood product conservation efforts and more than \$20 million by providing the best treatment to patients with atrial fibrillation at the right time.

Comments

On behalf of STS, I would like to thank you for your very thoughtful proposal. The Society is particularly grateful that our endorsement of specialty-specific processes for determining quality and efficiency that rely on risk-adjusted outcomes (using registry data and associated quality measures) has resonated with the committees of jurisdiction and has a prominent role in your discussion draft. STS wishes to commend this Committee and your colleagues on the Ways and Means Committee for taking the first steps toward meaningful physician payment reform. STS has provided substantial comments on the concept document released by the Committees on April 3 that we submit here for the record.

Access to Administrative and Outcomes Data

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 administrative data from CMS (and, hopefully, other payors) both for episode of care and longitudinal follow-up, as well as outcomes (death) data from the Social Security Administration or another, accessible source. It is imperative that SGR reform legislation address this foundational issue.

The ability to link clinical data with administrative data has opened up important new ways to assess the effectiveness of treatment options, and has 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. In addition, linking clinical registries to the Social Security Death Master File (SSDMF) once allowed 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 educate today’s patients and families so that they can play an active and informed role in the shared decision-making process. Valid and reliable outcomes data give patients confidence in their medical interventions and demonstrate to patients and their families the durability and long-term risks and benefits of medical procedures based on real-life, quantified experience rather than abstract concepts.

Unfortunately, CMS MEDPAR data have only been available for use in conjunction with the STS National Database on a project-by-project basis. Further, 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 linked administrative and outcomes data when placed in the right hands, with adequate protections in place. 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 combining records with outside sources, patient identification information is matched against other records, such as those in the SSDMF. The follow-up information is returned from external entities and linked back to the records in the de-identified database. 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.

Improving Care through Collaboration or Competition

With its nearly 25 years of experience providing the STS National Database, STS has considerable expertise in how a data collection and physician feedback mechanism affects surgical practice. For that reason, we have made specific recommendations to the Committee about the level of attribution at which data should be collected and incentives should be applied. In general, our approach to these issues is to use the tools available to facilitate collaboration and raise the bar for the entire specialty of cardiothoracic surgery.

If a quality-based payment system is designed to operate on the individual physician level, we fear that intra and inter-hospital cooperation and sharing of best practices will suffer.

Additionally, from a purely statistical perspective, it is virtually impossible to distinguish

different levels of performance between one clinician and another because the total number of patients / outcomes / events created by the individual practitioners is far too small to achieve any meaningful interpretation. Placing incentives at a higher level can encourage collaborative learning and quality improvement that should be inherent aspects of professionalism.

Finally, placing the focus on the individual practitioner or certain specialties detracts from the team approach to patient care that always has been the hallmark of our specialty (e.g., the heart team, the cancer team, etc.). In order for such a 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.

Building Critical Registry Infrastructure

STS is particularly grateful to this Committee for your recognition of the utility of clinical registries in pursuit of a pay-for-quality physician payment system. To that end, we recognize that Congress faces a challenge in that many specialties do not yet have the ability to collect clinical data, develop risk-adjusted quality measures, and implement physician feedback and quality improvement programs. That said, we hope that implementation of a pay-for-quality program will not have to wait for all of medicine to be at the same place at the same time. We believe that early innovators who are able to enter into Phase II should be able to reap some reward for their efforts. For that reason, we recommend that policy makers consider ways to reward providers for incremental steps towards these quality assessment and improvement goals

while allowing those medical professionals whose specialties that already have the requisite infrastructure in place to engage in this new system as soon as possible.

Doing so will provide an incentive for others to move in a similar direction more quickly.

Importantly, however, we believe that such a program can be structured so that physicians whose specialties are taking steps towards full scale implementation can reap some rewards. Short, medium, and long term infrastructure, measure, and quality assessment benchmarks should be set up as intermediate goals. For example, incremental steps towards Phase II readiness can include reporting of data to a clinical database under construction, working on various “Clinical Improvement Activities” as defined in the Committees’ concept document, and receiving feedback on quality measure performance (even while such measures are being considered for approval), among others.

Corollary Potential of Developing a Clinical Registry Infrastructure

In appreciation of this Committee’s work in favor of developing national clinical registry infrastructure, I wanted to point out for you some of the advancements in other aspects of health care policy facilitated by the STS National Database:

Medical Liability Reform: With respect to the Committee’s express intent to remain open to the discussion of medical liability reform, we believe that the proposal to develop a clinical registry infrastructure helps to lay the groundwork for tort reform that can protect patients and providers alike. STS believes that setting standards aligned with best practices identified by specialty societies is the best way to institute meaningful medical liability reform. 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.

Public Reporting: STS launched a Public Reporting Initiative in January 2011 in collaboration with Consumer Reports. As of March, 2013, 41% of Database participants voluntarily report their results for Coronary Artery Bypass Graft (CABG) and/or aortic valve replacement on the Consumer Reports or STS websites. STS is universally regarded as the medical professional society leader in these activities.

Medical Technology Approval and Coverage Decisions / Appropriate Use Criteria: The TVT Registry™ is a benchmarking tool developed to track patient safety and real-world outcomes related to the transcatheter aortic valve replacement (TAVR) procedure. Created by STS and the American College of Cardiology, the TVT Registry is designed to monitor the safety and efficacy of this new procedure for the treatment of aortic stenosis. The TVT Registry was instrumental in facilitating the approval and coverage with evidence development of new medical technology, helping to bring this technology to the marketplace safely and efficiently.

Comparative Effectiveness Research: The Patient Centered Outcomes Research Institute has recognized the value of “observational research” using clinical registries to fulfill its mission. Further, registries such as the TVT Registry can be developed and augmented to collect real time data to measure outcomes in different patient populations in real time. We believe that comparative effectiveness research can help physicians, in collaboration with patients and families, to provide the right care at the right time, every time.

Determining Value of Physician Services: 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.

Conclusion

With the Congressional Budget Office's current 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 this Committee to draft legislation for that purpose that recognizes and attempts to leverage the power of clinical registries. STS wishes to thank you for the collaborative nature of your process thus far, and requests that you move forward with continued openness to stakeholder input.

Further, inasmuch as those who currently participate in the STS National Database may already be able to meet the provisions in your proposal as outlined, we welcome the opportunity to get started. Understanding that others will need to develop the infrastructure to support such a program, it is our hope that specialties will be able to jump into the pay-for-quality world when

they are ready, rather than waiting for all of medicine to get to the same place at once. To that end, STS has valuable experience in registry development that we are able to share with those specialties undertaking the task of building a registry now or in the future.