THE SOCIETY OF THORACIC SURGEONS

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Mr. Michael Wroblewski
Bureau of Competition
600 Pennsylvania Avenue, N.W.
Washington, DC 20850

RE: "Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901"

Dear Mr. Wroblewski:

On behalf of The Society of Thoracic Surgeons (STS), I would like to take this opportunity to provide comments as a follow-up to the Federal Trade Commission's (FTC) Competitive Significance of Health Care Quality Information Workshop held in Washington, DC on October 30, 2008. The Society applauds the FTC for convening a group of qualified individuals undertaking the provision of up-to-date information, various perspectives, and discussion on these topics.

Background

STS believes it is important to provide some context for our following comments on quality measurement, improvement, and reporting. Our comments stress the importance of data-driven approaches to quality measurement, improvement, and reporting because we know that **the collection of clinical data and the feedback of those data to physicians can improve outcomes and result in cost savings**. STS has extensive experience with this due to our Adult Cardiac Surgery Database (Database) established in 1989. This national, voluntary database captures 100 percent of the surgical procedures for adult patients performed by cardiothoracic surgeons (participants) at various hospitals throughout the Untied States. With more than 960 participants representing more than 2,750 individual surgeons, STS estimates that the Database captures approximately 90 percent of adult cardiac surgery performed in the United States. Currently, the Database contains more than 3.6 million surgical records and is the largest clinical cardiac surgery database in the world.

Quality Measurement

Data Source

STS believes that every effort must be made to encourage the development of accurate clinical databases for use in any quality improvement and in any public reporting system. **Claims data**

are not sufficient to measure outcomes and are incapable of allowing adequate risk adjustment, resulting in inaccurate comparisons and the potential for major incorrect conclusions drawn from these data. Only a clinical database with a sufficient volume of clinical records can be risk adjusted for case mix to yield accurate and comparable findings.

The Society's standardized collection and reporting of clinical data for nearly 20 years has resulted in improvements in quality of care for cardiac surgery patients. To measure quality, STS developed a series of performance measures that were endorsed by the National Quality Forum (NQF). Kenneth Kizer described these as "the first set of national standardized performance measures to assess the performance and outcomes of cardiac surgery."

STS believes that all outcomes measures should be reported in risk-adjusted format to account for case mix variation across participants. To accomplish this STS has developed a series of risk models, which are available to the public on request. The models are both validated and peer-reviewed to ensure the highest possible degree of reliability. These models have recently been updated and are now in press. In three very detailed papers to appear in *The Annals of Thoracic Surgery*, the CABG, valve, and CABG + valve risk models are presented with specific mention of the intercept, the coefficients, and the formulas so that **the models are totally transparent**. In addition, STS maintains a Risk Calculator on its Web site (**www.sts.org**) whereby anyone can use the STS risk models to calculate mortality and/or morbidity for a given procedure.

The set of 21 NQF-endorsed measures forms the basis for measuring quality in cardiac surgery. These measures include structural, process, and outcomes measures, which STS uses as the basis for its **3-tier quality measurement report.**

The first tier includes 15 performance measures (those measures available in the Database when the reports were designed) reported at an aggregate level. The level can be the STS aggregate, that is, the performance of all STS Database participants providing data to the Database. This tier can also include data aggregated at a state or regional level. The performance across the15 measures can be used by interested constituents as references or benchmarks with which individual participant or hospital performance can be compared.

The second tier of quality measurement provides performance on the 15 NQF-endorsed measures at an individual participant (single cardiothoracic surgeon or group of cardiothoracic surgeons) or hospital level. Reports provide recipients with data about their performance relative to the overall STS performance as well as to where in the distribution a recipient falls.

The third and most recently developed tier is a rating system that assigns a participant a 1, 2, or 3 star rating based on performance on a composite quality measure. The STS composite measure appropriately weights and measures 11 of the NQF-endorsed measures for cardiac surgery and yields one composite score for each participating institution or practice in the STS Adult Cardiac Surgery Database. A 3 star rating means that, with 99% certainty, a participant's performance is better than the STS average, while a 1 star rating signifies that, with 99% certainty, the participant's performance is below that of the STS average. A 2 star rating means that a participant's performance, with 99% certainly, doesn't differ from the STS average.

Quality Improvement

Using this system, STS is able to measure quality and to provide a basis on which improvement can occur. One of the founding principles of the Database was that it be designed as a vehicle to facilitate and track quality improvement. Over the years, STS data have shown reductions in mortality rates in cardiac surgery by 70 percent below previously expected rates. STS, in collaboration with its National Database participants, has demonstrated the ability to continue to improve quality in adult cardiac surgery and to expand its quality improvement efforts in lung and esophageal cancer surgery and in surgery for children with congenital heart defects.

Setting Quality Improvement as the Primary Goal of Data Collection

The STS Database was designed for quality improvement purposes, not for quality assurance, whereby poor performers are penalized. STS believes, and has empirical data to support, that **feeding detailed clinical data back to physicians is what is most helpful for quality improvement**. Given the current focus on public reporting, STS opposes the use of quality data for the purpose of physician profiling, which serves to only exacerbate gaps in quality. STS acknowledges the need to reduce variation in care across the country. Rather than profiling, STS has shown that overall improvement in quality can best be provided by reducing variation among providers and improving performance across the board in all physicians by the use of a large clinical database. Surgeons with outcomes below their peers have an incentive to improve and a legitimate comparison in risk-adjusted outcomes. STS has established a workforce within its organizational structure, which is specifically dedicated to providing assistance and advice to members and their institutions who request it.

Value, not Cost

STS believes that risk adjustment is a critical element of any incentive payment or shared savings program and that the focus of these programs should be on value, not cost. To create value, the determination of quality in any program must depend on the clinical, risk-adjusted outcomes of services rendered or the adherence to care processes, with the outcomes and processes being determined by the NQF endorsement process. By focusing on increasing value, it is less likely that "cherry-picking" of low-risk patients will occur because risk adjustment will correct for variation in case mix. A focus on increasing value should also provide a disincentive for stinting on care if stinting results in poorer outcomes.

Achieving quality-based savings requires the development of clinical performance measures that are vetted through the consensus standard development process at NQF, as STS has done with its cardiac measure set. STS reiterates its position that quality or cost-efficiency measures used as part of any incentive payment or shared savings program be required to have NQF endorsement.

When appropriately risk adjusted, outcomes measures can be used to measure mortality and complication rates in crucial areas such as prolonged intubation, mediastinitis, stroke and renal failure. While measurement of patient outcomes is more difficult, given the necessity of risk adjustment and the high premium on data accuracy, **outcomes measures have the greatest ability to impact quality improvement and cost savings**. There is scientific literature that provides data to support this claim.

Most would agree that the STS Database is one of the most mature clinical databases in existence. With the advent of the Center for Medicare and Medicaid Services' (CMS) Physician Quality Reporting Initiative (PQRI), STS applied for and received approval from CMS to participate in registry-based reporting for the Adult Cardiac Surgery component of the STS National Database, meaning that STS, with Adult Cardiac Surgery Database participants' approval, can send their PQRI data directly to CMS without having to enter or report them twice. By this approval, CMS is sending the appropriate message that there is value in high quality, outcomes-focused, clinical registries and that **clinical data are the gold standard in performance measurement and quality improvement efforts**. Furthermore, because clinical data can be appropriately risk adjusted, clinical registries yield reliable processes and outcomes metrics that are clinically relevant, can be tracked over time, and can be integrated with other payer database systems.

Reporting

Institutional versus Individual Reporting

STS believes that the best results in data reporting occur at the institutional/practice level, given potential sample size errors at the individual practitioner level. Any reporting must be based upon clinical data – with outcomes data being appropriately risk adjusted – and should encompass multiple years of data to examine consistency of outcomes. If public reporting is done at the individual physician level, it must be limited to the reporting of measures over which the physician has control. For example, ordering beta blockers for CABG patients at the time of discharge is an appropriate measure to report at a physician level because the physician would generally be responsible for ordering the medication. However, whether a patient dies within 30 days of CABG surgery is not solely dependent on the cardiothoracic surgeon's operation, but rather on the entire health care team, patient compliance, and other post-operative factors.

Transparency

STS supports creating greater transparency and accountability among physicians but suggests proceeding with caution in the area of public reporting. Public reporting of outcomes at only the hospital level can avoid the unintended negative consequences of selection bias toward low-risk patients and "gaming" the reporting system with individual physician level reporting. To address transparency end and as noted earlier, STS has made its risk models totally transparent and publicly available. For those who elect not to recreate the risk models themselves, but want to determine the risk of mortality and/or morbidity for a given patient, the Risk Calculator is available on the STS Web site. All STS data definitions for the data elements collected in the Database are also on its Web site as are the software specifications for data collection. STS uses standardized data collection forms, which are also available on its Web site. Executive Summaries of current and historical data are available as well.

Use of STS Database Data

Participants in the Database own their data and are free to use them as they wish. STS has developed guidelines about how data are to be reported if comparison(s) are being made. In its Participation Agreements, STS outlines the conditions under which a participant is permitted to use/report STS data beyond those of the participant alone.

STS never provides a participant's data to a third party without the explicit written consent of the participant. This extends even to participation in CMS' PQRI program.

Consumer Information

Although complex to calculate, the STS quality composite measure, reported according to the star rating system described earlier, is sufficiently easy to understand, making it a potential measure suited for consumer or patient reporting. With analogies to restaurant, hotel, and even movie rating systems, STS is considering the utility of this measure for consumers.

STS believes that making CMS PQRI participation information available to the public is a good starting point, as CMS and medical societies work toward the collection of clinical data that will be most useful to physicians and patients.

On behalf of STS, I hope that this information adds to the understanding of the importance that clinical registries have in measuring quality, improving it, and contributing to consumer understanding of health care quality information.

Sincerely,

W. Randolph Chitwood, Jr., MD