

STS Headquarters

633 N Saint Clair St, Suite 2100
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org



Washington Office

20 F St NW, Suite 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacv@sts.org

March 20, 2018

Senator Bill Cassidy
520 Hart Senate Office Building
Washington, DC 20510

Senator Michael Bennet
261 Russell Senate Office Building
Washington, DC 20510

Senator Chuck Grassley
135 Hart Senate Office Building
Washington, DC 20510

Senator Tom Carper
513 Hart Senate Office Building
Washington, DC 20510

Senator Todd Young
400 Russell Senate Office Building
Washington, DC 20510

Senator Claire McCaskill
503 Hart Senate Office Building
Washington, D.C. 20510

Re: Health Care Price Transparency Initiative

Dear Senators Cassidy, Bennet, Grassley, Carper, Young, and McCaskill,

On behalf of The Society of Thoracic Surgeons (STS) and its members, I would like to provide feedback on your efforts to improve price transparency and lower costs in the health care market. Founded in 1964, STS is an international not-for-profit organization representing more than 7,300 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are part of the cardiothoracic surgery team. STS members are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other procedures within 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.

The Importance of Risk-Adjusted Outcomes in Assessing Cost

The STS National Database™, currently approved by the Centers for Medicare & Medicaid Services (CMS) as a Qualified Clinical Data Registry (QCDR), was established in 1989 as an initiative for quality assessment, quality improvement, and patient safety among cardiothoracic surgeons. The Database has four components—the STS Adult Cardiac Surgery Database, the STS General Thoracic Surgery Database, the STS Congenital Heart Surgery Database, and the STS Intermacs Database (mechanical circulatory support). 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 create the most powerful mechanism for change and improvement in the practice of cardiothoracic surgery for the benefit of patients. In fact, published studies indicate that quality of care has improved as a result of research and feedback from the STS National Database.¹²³⁴⁵⁶

The STS National Database has facilitated advancements in many aspects of health care policy, including National Quality Forum approval of 34 quality measures, public reporting of health care quality measures in collaboration with Consumer Reports, facilitation of medical technology approval and

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coverage decisions, and fostering cost savings that help cardiothoracic surgeons find the most efficient and effective way to treat patients.

Clinical data from the STS National Database have been linked with administrative claims data from CMS on a number of occasions, either as 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 offer novel avenues for future medical research. Clinical data mined from the STS National Database have the ability to yield sophisticated and accurate risk adjustment assessments; administrative data (i.e., claims data) provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs, creating serious limitations in their ability to construct accurate clinical risk adjustment models.

Combining claims data with clinical data and robust quality information such as that contained in the STS National Database is the key to value-based payment. Without the claims data, cardiothoracic surgery is a specialty at the cutting edge of quality improvement that cannot build off its successes by developing an alternative payment model.

One example of how an alternative payment model based on the combination of clinical and claims data has already been operationalized belongs to the Virginia Cardiac Services Quality Initiative (VCSQI). VCSQI is a voluntary consortium launched in 1996 that includes hospitals and cardiac surgery practices in the Commonwealth of Virginia. VCSQI currently has amassed a database by combining information from the STS Adult Cardiac Surgery Database for participants in Virginia with UB-04 financial records for more than 100,000 patients undergoing cardiac surgery; this means that clinical outcomes and financial cost records are available for more than 98% of all patients undergoing cardiac surgery in Virginia. As a result, evidence-based protocols for treatment of post-operative atrial fibrillation, transfusion reduction in cardiac surgery, early extubation following open heart surgery procedures, and glucose management have been developed with a savings of approximately \$90 million through a reduction of post-operative mortality and morbidity in cardiac surgery. This innovative VCSQI project demonstrates cardiothoracic surgery's ability to fuse clinical outcome measures with simple cost projections derived from claims data, thereby allowing for the creation of pilot models of alternative payment methodology.

What information is currently available to consumers on prices, out-of-pocket costs, and quality?

Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) requires CMS to provide QCDRs with access to Medicare data for the purposes of linking such data with clinical outcomes information and performing scientifically valid analyses or research to support quality improvement or patient safety. Unfortunately, to date, this section of the MACRA statute has not been implemented correctly. Therefore QCDRs are still unable to access Medicare claims data for quality improvement, research, or even alternative payment model design.

CMS initially decided not to issue rulemaking on this section of the law based on its assertion that QCDRs currently can request Medicare claims data through the ResDAC data request process. This position mistakenly assumed that Congress was not aware that QCDRs could apply for access to Medicare claims data through the ResDAC process and blindly directed CMS to provide QCDRs with access to data that were already available to them. CMS also ignored the fact that Section 105(b) is intended to provide QCDRs with access to Medicare data for quality improvement purposes, not just

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clinical research, and that the broad and continuous access needed for quality improvement purposes is fundamentally different than the access to Medicare data for research purposes provided by ResDAC. Providing QCDRs with regular and timely access to Medicare claims data is critical to the future of Medicare payment policy, which is now inextricably linked to quality improvement and resource use. It also will dramatically increase the power of clinical outcomes data collected by QCDRs and therefore yield immeasurable benefits for patient health and safety.

In subsequent rulemaking, CMS decided to treat QCDRs as “quasi-qualified entities” for purposes of obtaining access to Medicare claims data for quality improvement but maintained that QCDRs should use the ResDAC application process for research requests. While we appreciate CMS’s effort to provide QCDRs with an alternative means of accessing Medicare data, treating QCDRs as quasi-qualified entities does not allow the type of access contemplated by Section 105(b) of MACRA. Further, it is operationally nonsensical to require that QCDRs use two different processes for use of the same data to fulfill both the quality improvement and research functions of the statute.

Section 105(b) explicitly directs CMS to provide 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.” To perform data analysis for quality improvement purposes and patient safety, QCDRs require long-term and continuous access to large Medicare datasets so that they can better track clinical outcomes longitudinally. In drafting Section 105(b) of MACRA, Congress was aware of this need and, as such, specifically directed CMS to provide QCDRs with Medicare claims data “for purposes of linking such data with clinical outcomes data.” Qualified entity status lasts only for 3 years, and continued participation in the program requires re-application by submitting documentation of any changes to the original application. If the re-application is denied, CMS will terminate its relationship with the qualified entity. In addition, Medicare Fee-For-Service files are released quarterly on an approximate 5.5 month lag. Qualified entities must pay for each set of data they receive, which can become cost prohibitive over time.

While the new qualified entity regulations contain some provisions that may help expand QCDRs’ access to claims data, the onerous requirements and lengthy application process required to become a qualified or quasi-qualified entity stand as a substantial barrier for QCDRs to gain the data access mandated by Section 105(b). The statute was intended to recognize the QCDR certification process, which itself is appropriately long and arduous, as sufficient demonstration of fitness for receiving claims data from CMS. QCDRs maintain the strictest of privacy standards, among other things, and are proven to be legitimate and secure repositories of patient information.

The quasi-qualified entity program covers only the “quality improvement” portion of a QCDR’s access to claims data. If the same QCDR wanted to facilitate research combining cost and claims information, that QCDR would have to submit a separate application to ResDAC. In fact, if the QCDR already had the claims data in question through the quasi-qualified entity program, it would still need to apply and pay ResDAC for the same data.

At the same time, every new payment model released by CMS and the Center for Medicare and Medicaid Innovation includes a provision that hospitals and qualified participants would be able to access their own claims information and any additional information deemed necessary by the

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participant. Clearly, CMS understands the value of price transparency in health care, yet it is failing to implement statute that speaks to that purpose.

What information is not currently available but should be made available to empower consumers, reduce costs, increase quality, and improve the system?

As outlined above, Congress made Medicare claims data available to clinical data registries that meet the standards of a qualified clinical data registry as defined by CMS. CMS has failed to adequately implement this provision.

Different states have used different methods to work towards price transparency. What is the best quality and price information to collect for consumers and businesses?

While claims data alone do not paint a full picture of health care value, which is a function of quality over cost, an argument can be made for using claims data as opposed to provider submitted data which frequently represents charges. The information should cover all payers and providers and it should be easily accessible. Ideally, claims data alone should be presented with the caveat that it should not be misinterpreted as a proxy for value.

On the other side of the value proposition, STS already works in collaboration with Consumer Reports on STS Public Reporting.⁷ As a national leader in health care transparency and accountability, STS believes that the public has a right to know the quality of surgical outcomes. As a result, the Society established the STS Public Reporting initiative in 2010. This program allows participants in the STS National Database to voluntarily report their surgical outcomes on the STS website, the Consumer Reports website, or both. STS Public Reporting would be further augmented if STS quality data were integrated with claims data, as was intended under Section 105(b) of MACRA.

Who should be responsible for providing pricing information and who should share the information with consumers?

Ideally all payer claims would be publically available. Absent a larger agreement across the insurance industry and, at a minimum, CMS should provide these data for the Medicare program. It is also worth noting that providing information to consumers on actual charges will not help.

What role should all-payer claims databases play in increasing price and quality transparency? What barriers currently exist to utilizing these tools?

All payer claims databases should be ubiquitous and the data should be made available for combination with robust clinical data such as those contained in the STS National Database to facilitate true value assessment.

How do we advance greater awareness and usage of quality information paired with appropriate pricing information?

The STS Public Reporting program was developed in concert with Consumer Reports to create a user-friendly star rating system so that consumers can easily interpret quality results. Pairing with consumer-facing entities and creating user-friendly platforms are crucial to communicating information. Limited

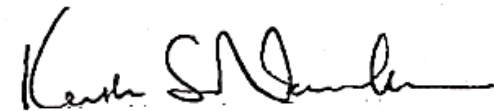
information, such as publication of claims data without quality information, should be clearly labeled as such and users should be made aware of the limitations of the resource.

How can our health care system better utilize big data, including information from the Medicare, Medicaid, and other public health programs, to drive better quality outcomes at lower costs?

This only can be truly accomplished if claims data are made available for integration with clinical data contained in robust clinical data registries. Absent that ideal scenario described above, CMS should provide claims data to the providers with a straightforward breakdown of inpatient costs, provider costs, post-acute care costs, home health costs, readmission rates, and costs. Given these data and local or regional (not necessarily national) benchmarks, providers (and patients) will have an idea where care can improve and where there are opportunities to cut costs. If benchmark prices from big data are created, the methodology employed should be clear and include stakeholders in the development.

STS appreciates your commitment to improving the nation's health care system. We look forward to working together on these important topics. Please direct any questions to Courtney Yohe, Director of Government Relations, at cyohe@sts.org or 202-787-1230.

Sincerely,



Keith S. Naunheim, MD
President

¹ElBardissi AW, Aranki SF, Sheng S, et al. Trends in Isolated Coronary Bypass Grafting: An Analysis of The Society of Thoracic Surgeons Adult Cardiac Surgery Database. *J Thorac Cardiovasc Surg* 2012;143:273-281.

² Speir AM, Rich JB, Crosby IK, et al. Regional Collaboration as a Model for Fostering Accountability and Transforming Health Care. *Semin Thorac Cardiovasc Surg* 2009;21:12-19.

³ LaPar DJ, Speir AM, Crosby, IK, et al. Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs. *Ann Thorac Surg* 2014;98:527-533.

⁴ Osnabrugge RL, Speir AM, Head SJ, et al. Cost, Quality, and Value in Coronary Artery Bypass Grafting. *J Thorac Cardiovasc Surg* 2014;148:2729-2735.

⁵ LaPar DJ, Rich JB, Isbell JM, et al. Preoperative Renal Function Predicts Hospital Costs and Length of Stay in Coronary Artery Bypass Grafting. *Ann Thorac Surg* 2016;101:606-612.

⁶ LaPar, DJ, Speir AM, Crosby IK, et al. Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs. *Ann Thorac Surg* 2014;98:527-533.

⁷ The Society of Thoracic Surgeons. STS Public Reporting Online. <https://publicreporting.sts.org>. Accessed March 20, 2018.