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June 8, 2020

The Honorable Lamar Alexander
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
154 Russell Senate Office Building
Washington, D.C. 20510

Re: 21st Century Cures 2.0 Concept Paper

Dear Senators Alexander and Murray,

On behalf of The Society of Thoracic Surgeons (STS) and its members, I would like to express support for Congressional efforts to modernize the healthcare delivery system. Founded in 1964, STS is an international not-for-profit organization representing more than 7,500 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 to provide the highest quality patient care through education, research, and advocacy.

The House has begun discussions to develop 21st Century Cures 2.0 legislation, as demonstrated by the recent Cures 2.0 Concept Paper released by Representatives DeGette and Upton. As you begin to consider similar legislation, we would like to raise your attention to the role such legislation could play in improving the ability of clinician-led clinical data registries to advance value in healthcare.

STS applauds efforts to modernize CMS coverage and care delivery and better utilize real-world data (RWD) and real-world evidence (RWE) in FDA approval processes. STS believes clinician-led clinical data registries (registries) are uniquely positioned to drive this change forward. The STS National Database, established in 1989 as an initiative for quality assessment, quality improvement, and patient safety among cardiothoracic surgeons, contains decades of clinical outcomes data. 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), as well as the STS/ACC TVT Registry (transcatheter aortic valve replacement and transcatheter mitral valve repair). The expansive clinical data included in these registries can contribute to modernization efforts as outlined in the Cures 2.0 concept paper. Unfortunately, existing regulatory barriers prevent these registries from accessing key claims data that would support Cures 2.0's modernization goals.

STS recommends including improved registry access to Medicare claims data in Cures 2.0. When combined with Medicare claims data, such registries will provide policymakers the missing link to achieve value in health care delivery systems and enhanced understanding of real world impact of new therapies across a broader patient base.

CMS Modernization and Opportunities to Improve Value

CMS modernization efforts have shifted focus toward value-based payment, as demonstrated by the CMS Innovation Center (CMMI)'s development of alternative payment models (APMs). Registries can play a key role in developing APMs, especially in highly specialized medical care, like thoracic surgery, that particularly benefits from modern technologies and innovation. As repositories of clinical data and robust quality information, such as that contained in the STS National Database, registries are key to developing APMs. Unfortunately, APM development requires an understanding of both quality and cost. Without 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.

There is demonstrated success developing alternative payment models based on the combination of clinical and claims data. The Virginia Cardiac Services Quality Initiative (VCSQI) is a voluntary consortium launched in 1996 that includes hospitals and cardiac surgery practices in Virginia. VCSQI 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. Essentially, the 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 led to 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.

For these innovative payment methodologies to be responsive to new technologies and therapies, it is more important than ever to gain a full understanding of health care value, which is a function of quality over cost. Registries have been trusted sources of quality and clinical outcomes for decades. However, without access to Medicare claims data, they lack a necessary component of the value formula: cost. Unfortunately, arduous and duplicative CMS regulatory processes place significant barriers for registries to access Medicare claims data that would fill in this cost information gap.

Real World Evidence

STS is encouraged by the inclusion of Real World Evidence (RWE) in the Cures 2.0 concept paper. Clinician-led registries are an essential source of RWE and provide vital information on patient outcomes. We also agree with your assertion that RWE holds a promising yet unfulfilled potential for use across federal agencies, including CMS and the FDA. In developing a federal government approach to identify ways other federal agencies can use RWE, registries can be a key RWE source.

Registries represent an opportunity to gain more insight into clinical outcomes for special and underrepresented populations. Given the large scale of data included in clinician-led registries, the scientific and medical community have an expanded capacity to learn more about the value of new therapies in these patient communities.

When combined with Medicare claims data, registry quality and clinical outcome data would be key to determining the value of emerging therapies, especially in historically underrepresented patient communities. Unfortunately, registry access to Medicare claims data remains unnecessarily limited without Congressional direction.

Regulatory Barriers
STS registries do not have access to Medicare claims data. As mentioned, access to Medicare claims data is essential for registries to fully contribute to CMS modernization efforts shifting toward value based payment and improved incorporation of RWE across federal agencies. Congress intended for certain clinical data registries to be able to request claims data from CMS for purposes of both quality improvement and research, as stated in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Instead, CMS has insisted that registries successfully complete two separate application processes to gain access to claims data for both of these purposes: the Qualified Entity Program and the Research Data Assistance Center (ResDAC).

Although the Quasi-QE program technically grants access to some Medicare data, the qualifying requirements and the restrictive parameters for data use have resulted in limited ability for registries to practically utilize such claims data. Quasi-QEs cannot use Medicare data for research purposes without submitting a separate research protocol to ResDAC for review and approval. Since these are bifurcated processes, registries are limited in how they can use the data for value improvement efforts, including Cures 2.0 initiatives, even when access is granted. It is important to underscore that the QE program allows data utilization for quality improvement, while ResDAC separately determines permission for research.

These repetitive, lengthy, and costly regulatory barriers slow down progress toward health care delivery system modernization. Even for those registries that obtain both types of approval, ResDAC has a three year time limit, at which point registries must return claims data and restart the application process. As you can see, this process does not contribute to efficiencies in the U.S. care delivery system or move closer to modernized value based payment.

Cures 2.0
By opening registry access to Medicare claims data, Cures 2.0 would establish a viable pathway to determining the value of innovative health care services and alternative payment models. Congress originally declared its intent to make this claims data available to registries in section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Unfortunately, to date, this section of the MACRA statute has not been implemented correctly and therefore limits the ability for registries to contribute data to determine value of healthcare services. Similarly, the 21st Century Cures Act defined the term “clinician-led clinical data registry,” with the intent of gathering quality and clinical data outcomes to better inform value based care. The Act defines a clinician-led clinical data registry as a clinical data repository that is led by clinicians and is designed to collect detailed, standardized data on medical procedures, services or therapies for particular diseases or conditions, provides feedback to its participating data sources, and meets certain quality standards. This standardized definition is particularly important for guaranteeing that electronic health record (EHR) patient data is only transferred to

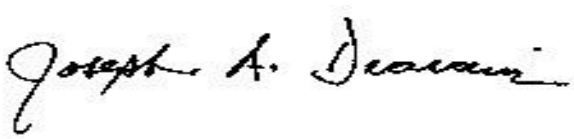
high quality registries that are fully capable of collecting, securing, and analyzing patient information for quality improvement. In fact, the definition establishes clear parameters for reviewing patient data that underscore how clinician-led clinical data registries are uniquely designed to be at the forefront of quality improvement initiatives.

Unfortunately, legislation to date has not provided a pathway for registries to access claims data for simultaneous quality improvement and research purposes, both of which are necessary to build an evidence-based shift to value based care. Cures 2.0 offers an opportunity to provide clarity and additional guidance to CMS to implement Congress's original intent in MACRA to improve registry access to Medicare claims data and therefore fully realize the potential of clinician-led clinical data registries.

STS recommends that Cures 2.0 guarantee clinician-led clinical data registries access to Medicare claims data for both quality improvement and research purposes to facilitate research, quality improvement, and alternative payment models that reward physicians for value, defined as quality over cost.

STS appreciates your commitment to improve the nation's health system. We look forward to working together on these important topics. Please direct any questions to Courtney Yohe Savage, Director of Government Relations, at cyohe@sts.org or 202-787-1222.

Sincerely,



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