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For Immediate Release

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STS Commends Clinical Data Registry Provisions in 21st Century Cures Act Statutory definition in new legislation may help improve patient care delivery and control costs

CHICAGO (December 9, 2016) — The Society of Thoracic Surgeons (STS) proudly recognizes the passage of the 21st Century Cures Act by the Senate Wednesday and the House last week. The bill, which President Obama said he'll sign as soon as it reaches his desk, will increase funding for disease research, support better mental health treatment, and help redesign the regulatory system for drugs and medical devices. Also important, the bill includes a statutory definition of a "clinician-led clinical data registry"—the result of an STS-led effort.

"This legislation has the potential to facilitate groundbreaking efforts in the area of health care quality improvement because it allows certain data registries—such as the STS National Database—to access information in the Electronic Medical Record," explained STS Secretary for Second Vice President Keith S. Naunheim, MD. "In the past, some EMR companies have had limited access to these data for purely proprietary or business reasons, which hampered our ongoing efforts to improve the quality of patient care and control health care costs."

Over the past year, STS has worked closely with the <u>Physician Clinical Registry Coalition</u> to define a clinician-led clinical data registry. The new definition exists in the context of leveraging EMRs to improve patient care.

Major features in the language include:

- "clinician-led": Data definitions will not be optimal without clinician leadership, nor will these definitions be accepted by the clinical community unless they have been involved in their development.
- "detailed, standardized data": This distinguishes clinical registry data from claims data, which have been insufficient, and EHR data, which are non-structured and non-standardized.
- "on an ongoing basis": This emphasizes the necessity for ongoing, longitudinal data collection. Much
 larger population cohorts are then available when constructing risk models and performance measures,
 and trends over time are more apparent.
- "provides feedback to participants": Neither claims data sources nor EMRs provide routine feedback to clinicians, yet this is the only way to derive the maximum value from any data source.

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- "meets standards for data quality": (A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and (B) being subject to regular data checks or audits to verify completeness and validity.
- "provides ongoing participant training and support": STS hosts an annual conference attended by
 more than 500 data managers. This provides an opportunity to increase understanding of Database
 specifications and to interact directly with clinicians and staff from STS and Duke Clinical Research
 Institute.

The STS National Database was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. One of its component databases, the STS Adult Cardiac Surgery Database, houses approximately 6 million surgical records and gathers information from more than 90% of the groups that perform cardiac surgery in the United States. Data from the Database facilitate nationwide quality improvement initiatives, allow robust public reporting via *Consumer Reports* and participant credit in *U.S. News and World Report's* ranking of best hospitals, and help guide patients and their families as they make health care decisions.

This legislation will mandate that the STS Database obtains access to the health care data necessary for an ongoing effort at quality improvement within cardiothoracic surgery.

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Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,400 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society's mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

About the Physician Clinical Registry Coalition

The Physician Clinical Registry Coalition is a group of 24 medical societies and other physician-led organizations that sponsor clinical data registries that collect identifiable patient information for quality improvement and patient safety purposes to help participating providers monitor clinical outcomes among their patients.

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