April 8, 2013

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3276-NC
P. O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs; CMS–3276–NC

Dear Acting Administrator Tavenner:

On behalf of The Society of Thoracic Surgeons, I write to provide comments in response to the Centers for Medicare & Medicaid Services’ (CMS) Request for Information (RFI) on the Use of Clinical Quality Measures (CQMs) Reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and other reporting programs.

The Society of Thoracic Surgeons 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 disease, 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 STS Adult Cardiac Surgery Database is the world’s premier clinical registry for cardiac surgery. The Database houses more than five million surgical records and gathers information from more than 90% of the approximately 1,100 groups that perform cardiac surgery in the United States. Anesthesiology participation is available within the Congenital Heart Surgery Database and will be added to the Adult Cardiac Surgery Database in 2013. In 2011, the Database expanded to include international participants; currently, Brazil, Israel, Turkey and Jordan have surgeons...
participating in the Database. STS also operates the STS/ACC TVT Registry™ in a joint effort with the American College of Cardiology (ACC). The fundamental principle underlying this 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. Studies indicate that the quality of care is improving. For example, ElBardissi and colleagues studied 1,497,254 patients who underwent isolated primary CABG at The Society of Thoracic Surgeons participating institutions from 2000 to 2009.

- Patients in 2009 had more preoperative diseases: compared with the year 2000, patients undergoing isolated primary CABG in 2009 were more likely to have diabetes mellitus (33% vs 40%) and hypertension (71% vs 85%).
- 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).
- Although predicted mortality rates of 2.3% were consistent between 2000 and 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%.
- The incidence of postoperative stroke decreased significantly from 1.6% to 1.2%, representing a 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.

In general, the STS National Database provides:

- a standardized, nationally benchmarked tool for assessing the care of patients undergoing cardiothoracic operations;
- the opportunity to participate in national quality improvement efforts for cardiothoracic surgery that have an impact at the local, regional, and national levels;
- a mechanism to target specific areas for clinical practice improvement;
- the ability to investigate regional and national practice patterns in cardiothoracic surgery; and

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1 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 The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), the TVT Registry is designed to monitor the safety and efficacy of this new procedure for the treatment of aortic stenosis. [https://www.ncdr.com/TVT/Home/Default.aspx](https://www.ncdr.com/TVT/Home/Default.aspx)

Duke Clinical Research Institute (DCRI) is the data warehouse and analysis center for the STS National Database. The DCRI team brings the STS National Database a wealth of experience and knowledge. On behalf of STS, DCRI develops robust participant-specific reports that provide analysis of participants’ outcomes and benchmark each participant’s data against regional and national scores. Importantly, STS leaders and Database participants have no involvement in the generation of quality scores for individual programs until they are published, thus eliminating any potential for interference with this process.

The Society has developed several dozen risk-adjustment models for cardiothoracic surgery, all of which were derived using granular clinical data from thousands of patient records. STS has also developed sophisticated quality performance measures in all three sub-specialties of cardiothoracic surgery, and 32 of these measures have either been endorsed or are in the process of being considered for endorsement by the National Quality Forum. In 2007, STS began developing a family of composite performance measures for the major procedures in CT Surgery, each one of which encompasses multiple domains of quality (e.g., mortality, morbidity, adherence to process measures). The STS National Database is regularly audited by an external, third party. Currently, 8% of all STS participant programs are audited annually.

Launched in 2011, the STS Research Center is a nationally recognized leader in outcomes research. The Center seeks to capitalize on the value of the STS National Database and other resources to produce cutting-edge research that provides the evidence base for cardiothoracic surgeons to improve surgical outcomes and the quality of patient care. The Database has also proven to be a powerful tool for clinical research. Since its inception, more than 150 publications have been derived from the Database. These studies have been published in a variety of professional journals and textbooks and have significantly advanced knowledge and patient outcomes in cardiothoracic surgery.

A new STS public reporting initiative was launched in January 2011, when more than 20% of Adult Cardiac Surgery Database participants began to voluntarily report their heart bypass surgery performance score to the public on www.sts.org. As of March 2013, approximately 41% of Database participants are voluntarily reporting their results for Coronary Artery Bypass Graft (CABG) and/or aortic valve replacement on the Consumer Reports or STS websites, and STS is universally regarded as the professional society leader in these activities.

As a general proposition, STS believes that the powerful clinical quality data harvested from registries such as the STS National Database can be leveraged to reform the current Medicare physician payment system to reward providers for healthcare quality. Such alternative Medicare payment methodology should align incentives along specialty or disease process lines at the regional or national level. This type of payment system would foster and incentivize physicians to act as members of a profession and fulfill their professional responsibilities to collaborate and share knowledge and practices with their peers. In that regard, STS believes that the most powerful and reliable method to affect physician practice is to engage physicians in the
collection of outcomes data on the services that they provide, and to provide meaningful, risk-
adjusted feedback that allows them to compare these outcomes to those of their peers.

Section 601(b) of the American Taxpayer Relief Act of 2012 (the statute allowing physicians to
report clinical data to certified clinical registries to fulfill their PQRS requirements) and the
potential expansion of that policy to align all CMS quality reporting programs, represent an
important step toward achieving Medicare payment reform. STS appreciates that Congress and
CMS have agreed to recognize clinical registries in this way and, in so doing, incentivize broad
adoption of clinical registries. While there is work to do to build a clinical registry infrastructure
to support a quality-based payment system, this policy is an important first step.

Responses to Specific Questions:

1) **Current CMS quality reporting requirements; examples of non-federal quality measure
collection activities; and allowing third-party entities to report quality data to CMS on behalf
of physicians:**

   How are the current reporting requirements for the PQRS and the reporting requirements in
2014 for the EHR Incentive Program similar to the reporting requirements already established
for the ABMS boards or to other non-federal quality reporting programs? How are they
different? In what ways are these reporting requirements duplicative and can these reporting
programs be integrated to reduce reporting burden on eligible professionals?

The American Board of Thoracic Surgery requires participation in an outcomes database for
maintenance of certification (MOC) part IV, and the STS National Database is approved by
ABTS for this purpose.

As noted earlier, STS currently estimates that greater than 90% of adult cardiac and congenital
cardiac cases are being reported to the STS Databases. Data from the ABTS show that 72% of
diplomates are currently using the STS Databases as their registry to fulfill the relevant
requirements for MOC. In some situations, particularly New York State and Washington, state
data registry requirements are accepted by the ABTS in order to reduce the data reporting burden
for diplomates from those states. The ABTS requirements for “acceptable databases” are that it
must be a large, multi-institutional recognized database with published database elements and
results. These acceptable databases must also collect important demographics, diagnosis,
procedures(s), pre-operative risk factors, intra-operative events, postoperative events, and
morbidity measures as well as mortality, be risk-adjusted, audited and cover the core elements of
adult cardiac surgery, general thoracic surgery, or congenital cardiac surgery. Finally, they must
include outcomes benchmarking.

It should be noted that PQRS only requires reporting compliance with process measures. It does
not promote or necessarily support quality improvement and does not measure or even capture
patient outcomes.
Are there examples of other non-federal programs under which eligible professionals report quality measures data?

Several states, third party payors, state quality collaboratives, and healthcare systems utilize STS National Database outcomes. In addition to its own public reporting initiative, STS Public Reporting Online, STS has partnered with Consumer Reports to provide consumers with a composite quality score for heart surgery. For example, the STS CABG composite score is calculated using a combination of 11 measures of quality divided into four broad categories or domains.

The Society’s star rating system, which is used in current public reporting efforts in published collaboration with Consumer Reports, is based on results from The Society of Thoracic Surgeons CABG Composite performance measure. The rating system is comprised of three rating categories: three stars, better than average performance (10-15 percent of hospitals); two stars, average performance (70-80 percent of hospitals); and one star, worse than average performance (10-15 percent of hospitals). Because of the robust nature of STS composite metrics, percentages of above and below average outliers are far higher than in most public reporting programs in healthcare (e.g., Hospital Compare). Because participating groups have the opportunity to add their case data to the Database four times a year, there is always up-to-date information about each program.

What would be the benefits and shortcomings involved with allowing third-party entities to report quality data to CMS on behalf of physicians and other eligible professionals?

We believe that an outcomes-based/data driven approach to care should be encouraged and supported, and that specialty societies are the only entities capable of generating relevant and clinically meaningful measures that are widely accepted by all stakeholders, including providers and patients. The ideal source for such data are clinical registries designed by content experts—the physicians and surgeons in a particular specialty. Sufficiently granular information should be collected to ensure robust risk-adjustment so that practices and hospitals caring for sicker patients are not penalized. Similarly, specialties will determine the most appropriate outcomes to measure, in most instances focusing on objective outcomes measures such as death and complications. A mechanism such as the STS National Database 1) takes advantage of an existing, nationally standardized, and validated data infrastructure, 2) minimizes duplication of quality reporting mechanisms, and 3) provides a method for reporting transparency among providers. It is, however, essential that any 3rd party database be carefully audited by an external entity to maintain the integrity of the database and the process of quality improvement. In the

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3 http://www.sts.org/quality-research-patient-safety/sts-public-reporting-online
4 Under contract with CMS, STS recently completed development of a 30-day all cause readmission measure for CABG based on the STS National Database. It is hoped that this measure will be used by CMS if CABG readmission rates are monitored using its Value-Based Purchasing Program.
case of STS, we contract with Telligen to randomly audit 8% of all STS participant programs annually, and we intend to increase the percentage of sites audited to 10% next year.

There must be a central review process, such as the process utilized by the National Quality Forum (NQF), to ensure the measures chosen by each specialty are valid and meaningful. The AMA Relative Value Update Committee and Physician Consortium for Performance Improvement are also examples of entities that utilize processes that are transparent and evidence-based. Entities utilizing these types of processes should be selected to advise the Secretary on the appropriateness of measures utilized by qualified registries.

In the short term, such a system realistically would be associated with penalties for failure to engage in the development of the data infrastructure that is necessary to achieve quality and clinical improvement goals. At a later developmental stage, this system may be linked to trends in such activities (i.e., failure to achieve such goals over several consecutive reporting periods rather than linked to each period) or stipulate provisions for averaging outcomes over time. It should be equally obvious that the more specific or discreet such systems are, the more costly they might be to administer.

Local variances in outcomes will be expected at the inception of such activity of reporting as a result of such a wide disparity of treatment plans and practices for all clinical entities. As seen with our own specialty, this variability will be reduced over time with the implementation of Observed to Expected ratios, comparisons of outcomes to national standards rather than local outcomes, and development of evidenced-based guidelines that will reduce variation in practices. Such methodology should also be tied to financial outcomes to document the fiscal impact of such variances through linkage of clinical registries with administrative claims datasets. The intent should be to have national performance norms. To the extent that local variances in outcomes are the result of local variations in primary disease process and co-morbid conditions, then robust risk-adjustment should account for these local variances.

Clinical data registries are often limited to short-term outcomes. To mitigate this limitation, STS links our clinical registry data to administrative sources such as CMS MEDPAR to obtain long-term clinical outcomes. Similar linkages could provide cost data, thus permitting assessment of resource use and value. The linkage of robust, risk-adjusted clinical data with resource utilization data provides the mechanism to assess the value of care being delivered. We anticipate that feedback of this data to the practice/institutional level will be associated with further improvements in the quality and cost, i.e., value of cardiothoracic surgical practice. We urge that the CMS MEDPAR data be made available on a regular basis to qualified registries which have robust patient privacy protections, such as the STS Databases.

In addition, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the Social Security Death Master File (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 SSDMF data. Linking clinical registries to the SSDMF allows for the verification of “life status” of patients who otherwise would be lost for follow up after their treatment.
Research based on this information helps physicians to provide information to today’s patients and families to help them with shared decision making. Outcomes data give patients confidence in their medical interventions and demonstrate to patients and their families the durability and long-term benefits of medical procedures. 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 the follow-up information is returned from external entities, such as the SSDMF, it is linked back to the records in the de-identified database, but the flow of information is only in this direction. The externally derived data are used to supplement the data in the individual record, but these data never leave the database except in de-identified form.

**What entities have the capacity to report quality data similar to those reported under the PQRS, Value-based Payment Modifier, and/or EHR Incentive programs? If these entities were to report such data to CMS, what requirements should we include in the reporting system used by such entities, including requirements to ensure high quality data?**

- Entities should self-nominate for evaluation that includes the following criteria:
  - An attestation statement with each submission,
  - A Data Validation Plan including data quality checks and audits, and
  - An annual Data Validation execution report.
- Once accepted, an accepted registry should remain a qualified entity as long as it meets the criteria above.
- Accepted entities must have the appropriate level of infrastructure necessary to collate and analyze performance measures and outcome data.

**How should the CMS quality reporting programs change/evolve to reduce reporting burden on eligible professionals, while still receiving robust data on clinical quality?**

- CMS should recognize and utilize audited data registries developed by and for medical professionals that meet ABMS requirements for MOC and meet the criteria outlined above in order to successfully report high quality data to CMS.
- Specialty-specific metrics will ensure that reporting, analysis, and quality assessment is meaningful and useful for all providers.
- Specialty-specific registries will yield national benchmarks and provide metrics that can be used for public reporting.
- Very careful consideration must be given to what core measures will be tracked and how easy is it for the clinical organization or physician to submit the data. Forms that are too complex or too long may lose accuracy and impact. Each specialty society must have a process that continually monitors accuracy and compliance.
- CMS should work with other relevant agencies to address privacy regulations that impede the collection of data through linkages. Such linkages are key to maximizing the value of clinical registries by providing long-term clinical and resource-use data.
2) **Reporting requirements for entities that report via a registry under the PQRS or the EHR Incentive Program if registry reporting is established as a reporting method in future years:**

*What types of entities should be eligible to submit quality measures data on behalf of eligible professionals for PQRS and the EHR Incentive Program? What qualification requirements should be applicable to such entities?*

- Clinical registries with standard data definitions, a robust data set, and risk-adjustment capabilities as previously described.
- A robust external audit.
- Ample participation on a national level to include not less than 30% of providers in that specialty.

*What functionalities should entities qualified to submit PQRS quality measures data possess? For example, for CQMs that can be electronically submitted and reported under PQRS and the EHR Incentive Program, should an entity’s qualification to submit such measures be based on whether they have technology certified to ONC’s certification criteria for CQM calculation and/or electronic submission?*

Although STS has concerns about the implementation of the current EHR incentives program, we feel strongly that CMS could take advantage of this opportunity to align all of the clinical quality measures reporting programs under its jurisdiction. We appreciate that Section 601(b) of the American Taxpayer Relief Act of 2012 provides the opportunity to leverage the power of clinical registries in order to help providers meet the goals of the existing PQRS program – healthcare quality improvement. We believe that CMS should allow registry-based CQM reporting to meet the standards for CQM reporting under meaningful use of EHR.

*What criteria should CMS require of entities submitting quality measures data to the agency on behalf of eligible professionals?*

Examples might include:

- Granular, nationally representative clinical data,
- Robust external audit,
- Performance measure transparency,
- Frequent feedback reports,
- Ability to report aggregate data,
- Benchmarking data, and
- Data auditing by external, third party.
Should reporting entities be required to publicly post performance data?

These efforts should initially be conducted on a voluntary basis. CMS should consider ways to incentivize public reporting of meaningful quality information that is based on specialty-specific clinical registries in place of current efforts to publically report (like Physician Compare).

Should CMS require an entity to submit a yearly self-nomination statement to participate in PQRS?

STS believes that an accepted registry that has self-nominated and successfully completed a rigorous vetting process described above should be qualified for these purposes for at least two years.

What should be included in the data validation plan for these reporting entities?

STS believes that a data validation plan should include both an internal and external component to ensure data integrity. Quality checks should be built into the database to identify and prevent acceptance of common data irregularities, duplicate records, incomplete records or inconsistent data. Participants should be provided with feedback on the quality of data submitted and required to correct errors prior to file acceptance. Independent external data audits should be required of at least 5 percent of cases.

If CMS provided a reporting option for PQRS and/or the EHR Incentive Program through such entities, what specification should CMS use to receive the quality data information (for example, Quality Reporting Document Architecture [QRDA] 1 or 3, XML, other)?

While STS would prefer XML format, we do not believe that Section 601(b) of the American Taxpayer Relief Act of 2012 is intended to augment the current PQRS program that allows clinical registries to report to PQRS on behalf of participating providers. Rather, the program is intended to identify more clinically meaningful and robust clinical registries that can achieve the intended goals of the PQRS program – to improve the quality of care provided to Medicare beneficiaries.

Should data submission timelines for these reporting entities be modified so that the submission timeframes for these quality reporting programs are aligned? For example, PQRS qualified registries are required to submit quality measures data once, within 2 months following the reporting period. How much time are reporting entities outside of PQRS afforded to submit quality measures data? What challenges do reporting entities face in reporting data according to current timeframes?

We believe the timeline for reporting should depend on the degree of analysis required. PQRS should allow 3 months after the reporting period ends to allow data analysis and validation. Current measures involving infection surveillance and readmissions require an interval post discharge of at least 30 days.
What oversight should be in place to ensure that data is submitted and calculated properly by entities?

A data validation execution report should be required to ensure quality checks were completed and the required cases and elements were submitted.

3) Selection of measures related to registry reporting under PQRS for 2014 and subsequent years and for the EHR Incentive Program if registry reporting is established as a reporting method for that program in future years:

Should CMS require that a certain proportion of submitted measures have particular characteristics such as being NQF-endorsed or outcome-based?

Yes, a high proportion should be NQF endorsed.

Should CMS require that the quality measures data submitted cover a certain number of the six national quality strategy domains?

These requirements would vary by specialty and measure focus. Not every domain will be covered in each case. For example, STS is extremely well represented in the areas of efficient use of healthcare resources and clinical process effectiveness, but currently we do not collect data on long-term care coordination, which is less relevant for procedures.

To what extent would third-party entities struggle to meet reporting for measures currently available under PQRS and EHR Incentive Program?

It is STS’s experience that the construction of a robust clinical registry requires significant personnel, data storage, and data validation resources. The development of the STS clinical registries has occurred over two decades and has been entirely funded by the participating institutions and practitioners. If the Federal Government incentivizes the development of similar registries for all specialties, then it is likely that these clinical registries will be developed with all of the known advantages over datasets based only on administrative claims data, including credibility among the providers in that specialty.

However, per the statement below, and given CMS’s opportunity to align all quality reporting programs under its jurisdiction, we encourage CMS to implement Section 601(b) of the American Taxpayer Relief Act of 2012 as it was intended – as a way to recognize more meaningful quality data reporting initiatives. Third-party entities should not be required to meet reporting requirements currently enforced under PQRS and EHR. Rather, new requirements should be put into place so that third-party entities that collect relevant quality data can help physicians to meet the quality improvement goals of the existing clinical quality measures reporting programs.
4) Registry measures reporting criteria:

We believe that Congress included Section 601(b), “Advancement of Clinical Data Registries to Improve the Quality of Health Care,” in the American Taxpayer Relief Act of 2012 because it recognized the limitations of the current PQRS program. Clearly, policy makers have identified that quality measurement and reporting is a critical component of the provision of healthcare to Medicare beneficiaries. PQRS was designed to help address this issue. However, CMS is ill-equipped to assume full responsibility for such an effort inasmuch as CMS cannot be a full-time clearinghouse of clinical quality measures for all medical specialties. In identifying preliminary quality measures for the PQRS program, CMS has effectively rendered the majority of medical specialties incapable of participating in the program meaningfully. By allowing medical specialties to develop their own, clinically meaningful, fully risk-adjusted, audited, outcomes-based registries and generating their own clinical quality measures (that meet rigorous standards imposed by CMS) we feel that Congress and CMS will increase the utility of quality reporting exponentially.

We caution CMS not to endeavor to fit the new mandate from Congress within the confines of the current PQRS program. To do so would be attempting to fit a much more robust and successful “peg” into a very rigid and ineffective (yet similarly shaped) policy “hole.”

Additional Comments

Use of clinical data registries to improve the quality and efficiency of care in the Medicare program

Section 601(b) of the American Taxpayer Relief Act of 2012 also directed the Comptroller General of the United States to conduct a study on the potential of clinical data registries to improve the quality and efficiency of care in the Medicare program, including through payment system incentives.

STS believes that any modernization of the Medicare payment system should ensure that individual medical specialties can—and have incentive to—control the growth rate of their services and payments by identifying the most effective and appropriate treatment for the patient. At the very least, specialties should not be penalized if their quality and value improvement activities result in a lower Medicare utilization and expenditures. As the STS National Database and registries of other specialties have demonstrated, feedback of credible, risk-adjusted outcomes data encourage physicians to change their practice patterns to achieve better outcomes, more efficient care delivery, and thereby, increased patient value. The following should be included in any Medicare physician payment reform initiatives:

- Mandate and incentivize the development and utilization of clinical data registries;
- Require that CMS and other payers to make administrative (cost and claims) data available to registries for use in their analyses so that resource utilization becomes an outcome variable to be assessed in the same manner as traditional clinical outcomes such as mortality or complication rates;
- Address barriers imposed by federal and state privacy regulations;
• Allow physicians to share the savings generated by their quality improvement efforts and consider providing economic incentives and disincentives at higher level than the individual physician or practice;
• Utilize registries and other resources to generate comparative effectiveness research; and
• Consider significant changes to reimbursement systems for both hospitals and physicians that promote wise use of resources and improved clinical outcomes.

The following policies, among others, relative to the development and utilization of clinical data registries in Medicare physician payment reform, require specific action:

• Require that and other payers to make administrative (cost and claims) data available to registries for use in their analyses so that resource utilization becomes an outcome variable to be assessed in the same manner as traditional clinical outcomes such as mortality or complication rates.

STS believes that meaningful quality measures and rewards for physician performance cannot be applied simply to administrative data reported by hospitals and physicians. While administrative data provide information on longitudinal medical treatment and resource utilization across settings of care and by various physicians, their clinical accuracy have been shown to be poor, and they excludes pertinent information on patient risk factors, disease severity, or clinical outcomes. This critical information is only found in clinical datasets where there is input of clinical data by clinicians. It is only by linking administrative and clinical data that we can appropriately and accurately assess whether physicians are improving patient outcomes and providing better value. STS urges CMS to consider quality incentive programs that facilitate the linking of Medicare claims data with existing registries to enhance patient monitoring and physician performance, and thereby to provide the data with which to improve quality. Without linking the administrative data collected by health plans and CMS with the clinical information reported by clinicians, patients cannot be effectively and comprehensively monitored. By using linked longitudinal registries, physicians can more broadly monitor patients for readmissions or care transitions. Similarly, longitudinal patient histories allow physicians to assess the success of cardiothoracic interventions.

• Address barriers imposed by federal and state privacy regulations

Healthcare providers are now being required to produce objective evidence of the quality, safety and value of care to a variety of healthcare stakeholders. These quality related efforts necessitate the collection, analysis and reporting of clinical data. Meaningful data collection often relies on the ability to use individually identifying patient information (particularly in analyses related to the value or sustainability of treatment interventions) in a careful manner that protects patient privacy. Risk-adjusted data collected in this way reliably results in the generation of new knowledge. The latter is a necessary and important aspect of quality improvement. The current regulatory structure fails to recognize that data collection for quality improvement purposes (including the retention of Personal Health Information) and the generation of “new knowledge” pose no substantial risk to the patient. In the STS National Database environment, the only risk that may exist is informational i.e., that the individual patient’s record exists in a clinical
database. As the HIPAA Privacy Rule already addresses many of these informational risks by imposing restrictions on how certain identifiable health information collected by health plans, healthcare clearinghouses, and healthcare providers (“covered entities” and their “business associates”) may be used and disclosed, it would seem extraneous and counterproductive to societal interests to hold quality improvement (QI) efforts such as clinical registries to Common Rule consent requirements if they already comply with HIPAA patient protections.

STS requests that CMS work with the Office for Human Research Protections (OHRP) and Office for Civil Rights (OCR) to establish appropriate standards for QI activities that will both adequately protect patients without unnecessarily burdening QI efforts. Until that guidance is made available, it is inevitable that significant variability in interpreting and applying the Privacy and Common Rules will persist. Specifically, we ask that OHRP issue guidance that the Common Rule does not apply to the collection and analysis of identifiable patient information for quality assessment and improvement purposes where the entities collecting and analyzing the data (such as clinicians and a corresponding clinical data registry) are engaged in standard patient care and are in compliance with all applicable HIPAA requirements. Moreover, we ask that definitive language be included in federal guidance to allow for a clear differentiation between “human subjects research” and the processes related to the essential prospective analyses directed at advancing our national quality care objectives. In particular, the generation of new knowledge should be recognized as an expected and desired outcome of healthcare quality improvement projects; the processes related to the generation of such knowledge should therefore be exempt from a requirement for informed consent (on the basis that all HIPAA related regulations are adhered to in the course of clinical data collection and analysis).

Thank you for the opportunity to provide comments to CMS in response to this Request for Information. If you need further information, please contact Phil Bongiorno, STS Director of Government Relations, at pbongiorno@sts.org or 202-787-1221.

Sincerely,

Douglas E. Wood, MD
President