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
advocacy@sts.org

June 20, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: [CMS–1694–P] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Administrator Verma,

On behalf of the members of The Society of Thoracic Surgeons (STS), I am writing to provide comments on the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates as published in the *Federal Register* on May 7, 2018. STS appreciates the opportunity to comment on this important rule.

Founded in 1964, STS is a not-for-profit organization representing more than 7,400 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical 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.

STS offers the following comments regarding the proposed changes outlined in the Notice of Proposed Rulemaking.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers*

A. Hospital Inpatient Quality Reporting (IQR) Program

The Centers for Medicare and Medicaid Services (CMS) seeks comment on two potential future measures for the Hospital IQR Program:

** Heading numbers correspond to sections in the proposed rule*

- Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure (MUC17-195);
- Hybrid Hospital-Wide Mortality Measure Electronic Health Record Data (MUC17-196)

These measures derive results from 13 mutually exclusive service-line divisions, including cardiothoracic surgery, and have separate risk models for each division. The hybrid version of the measure differs from the claims-only measure in that aspects of it would be electronically extracted.

Although a measure of hospital-wide mortality might capture a hospital's performance across a broader set of patients and across more areas of the hospital, we are concerned about the risk adjustment methodologies applied to these measures and whether they are adequate to protect hospitals that are already at a disadvantage because of their more complex and higher risk patients. We agree with the MAP that these measures should not be considered for implementation until after they have been reviewed and endorsed by the National Quality Forum (NQF) to ensure they have appropriate clinical and social risk factors in the risk adjustment models. We also remind CMS of the limitations of claims-based data. Although both versions rely, to some extent, on claims data, the hybrid approach is preferred because of its ability to incorporate more clinically relevant data than what can be captured through administrative claims. As CMS continues to refine these measures, we also recommend that it consider the use of specialty-specific registry data.

D. Proposed Changes to the Medicare and Medicaid EHR Incentive Programs (now referred to as the Medicare and Medicaid Promoting Interoperability Programs)

CMS proposes to rename the Hospital Medicare and Medicaid Electronic Health Record Incentive Program ("Meaningful Use") to the Promoting Interoperability (PI) Program. It proposes to minimize the physician reporting burden by reducing the number of required measures from 16 to 6 and permit a minimum 90-day reporting period for 2019 and 2020. CMS also proposes to move from a threshold-based scoring system to a performance-based scoring system, similar to the Merit-Based Incentive Payment System (MIPS), and to require hospitals to use 2015 Edition Certified EHR Technology **(**CEHRT) in 2019.

While STS supports the proposals aimed at minimizing reporting burden and furthering alignment with MIPS, we are concerned about mandating the use of 2015 Edition CEHRT in 2019 among both hospitals and clinicians. We recognize that the 2015 Edition includes important updates to more comprehensively support the seamless exchange of data and support incentives to move providers in that direction. However, the reality is that upgrading to the new Edition is expensive and time consuming, particularly for small and rural providers. Providers should be incentivized, but not forced, to upgrade to recognize the diversity of practice types.

STS also recommends that CMS consider broadening the scope of this program, as well as the Performance Improvement (PI) Category under MIPS, so that it recognizes innovative ways of harnessing, sharing, and otherwise employing health data to improve clinical outcomes. The current set of programs focuses heavily on electronic health record (EHR) functionality, but

largely ignores the more robust collection of data by registries, particularly the STS National Database, which is often translated for use at the point of care.

CMS also proposes to add two new opioid-focused measures to the Hospital PI program, which would be voluntary in 2019 and required in 2020: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. While we fully appreciate the intent of these two measures, we believe there are too many ongoing challenges related to e-prescribing of Schedule II opioid prescriptions and the ability of EHRs to easily query a PDMP. State laws still vary widely, as does user experience with PDMPs across the country.

X. Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet

In the proposed rule, CMS states, "in order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under section 2718(e) of the Public Health Service Act." The requirement that hospitals publish a list of standard charges for items and services is just one of the tools employed in Section 2718(e) of the Public Health Service Act to ensure that consumers receive value for their premium payments. Yet it has also become increasingly clear that CMS has struggled to adequately define value in health care. To better facilitate value transparency, the proposed rule attempts to address problems with the agency's ability to define and make publicly available information relevant to the cost side of the value equation: namely a list of standard hospital charges for items and services. While the comments that follow address how CMS can further facilitate cost or "price" transparency, we would note that CMS has also struggled with publicly communicating the quality side of the equation in a way that can be useful to patients, even when reliable data exists.

While defining quality measures for Medicare providers under the various physician fee schedule payment models has been a challenge, CMS continues its reluctance to rely on quality measures developed by medical specialties that have been demonstrated to improve quality. The STS National Database™ 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.[i] [ii] [iii] [iv] [v] [vi]The STS National Database has facilitated advancements in many aspects of health care policy, including NQF approval of 34 quality measures, public reporting of health care quality measures in collaboration with Consumer Reports, facilitation of medical technology approval and coverage decisions, and fostering cost savings that help cardiothoracic surgeons find the most efficient and effective way to treat patients. However, CMS has been reluctant to rely on these tried and true measures of quality, opting for measures that are far less meaningful to patients and to surgeons who are trying to improve the care they provide.

Recent reports indicate a variety of problems with the accuracy and reliability of hospital star ratings that CMS has been publishing since 2016.[vii] These star ratings are intended to help patients' evaluate hospitals so that they can determine where they are likely to get the highest quality care. However, due to the issues recently identified, CMS decided to postpone the July release of its hospital star ratings data. Here again, with respect to cardiothoracic surgery, CMS is attempting to recreate the wheel. 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[viii]. 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. These star ratings were even published in Consumer Reports.

In the proposed rule, CMS further states that "we are also considering other potential actions that would be appropriate, either under the authority of section 2718(e) of the Public Health Services Act ***or under another authority"*** (emphasis added). CMS also asks "What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interacts with these data?

The Society is in agreement with CMS that the most valuable tool for patients who are interested in making proactive choices about their health care is value transparency. Fortunately, the STS

---

[i] ElBardissi 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.

[ii] 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.

[iii] 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.

[iv] 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.

[v] 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.

[vi] 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.

[vii] Castellucci, M. (2018, June 15). *CMS Star Rating System has been Wrong for Two Years, Health System Finds*. Retrieved from Modern Healthcare: http://www.modernhealthcare.com/article/20180615/TRANSFORMATION01/180619933?utm_source=modernhealthcare&utm_medium=email&utm_content=20180615-TRANSFORMATION01-180619933&utm_campaign=am

[viii] The Society of Thoracic Surgeons. STS Public Reporting Online. https://publicreporting.sts.org. Accessed March 20, 2018.

National Database already provides for quality transparency through STS Public Reporting online. If CMS were to adequately implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), we would have access to Medicare claims data, or the cost denominator of the value equation. Unfortunately, the programs CMS has offered to implement that section of statute are not working.

Section 105(b) of MACRA requires CMS to provide Qualified Clinical Data Registries (QCDRs) with access to Medicare data 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. 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 ignored the fact that Section 105(b) is intended to provide QCDRs with access to Medicare data for quality improvement purposes, not just 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. 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.

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. 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 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 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. The ResDAC application is

duplicative, time-consuming, and costly, with a significant lag between application approval and delivery of 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 should be able to access their own claims information and any additional information deemed necessary by the participant. Clearly, CMS understands the value of price transparency in health care, yet it is failing to implement statute that speaks to that purpose.

If CMS is truly interested in using its existing authority to provide information on the value of health care to the Medicare population, it will take another look at how it is implementing Section 105(b) of MACRA. Absent that ideal scenario, 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 improve efficiency. If benchmark prices from big data are created, the methodology employed should be clear and include relevant stakeholders in the development.

XII. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid Participating Providers and Suppliers

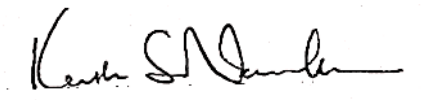
In this rule, CMS requests information on how it could use the CMS health and safety standards that are required of providers participating in Medicare and Medicaid (e.g., Conditions of Participation (CoP) and Conditions for Coverage) as a way to advance the electronic exchange of information and support effective transitions of care between hospitals and community providers. Revisions to the current CMS CoPs for hospitals could include: requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (e.g., required discharge instructions) via electronic means if requested.

STS agrees that more must be done to advance the electronic exchange of information, particularly between hospitals and community providers. However, the CoP process would be difficult at a time when real barriers continue to exist, many of which are outside of the direct control of the hospital and provider. Prematurely mandating data exchange could unintentionally limit patient access to care if the Medicare participation status of more resource-strapped facilities is jeopardized. We remind CMS that the Office of the National Coordinator (ONC) is about to make proposals on ways to implement sections of the 21st Century Cures Act that will address interoperability, information blocking (including penalties for blocking by providers and HIT developers), and patient access to health information. We request that CMS first give the

public the opportunity to respond to these proposals, and for ONC to test some of these new policies, before considering more drastic measures such as mandating data exchange as a condition of participation.

STS appreciates the opportunity to provide comments on proposed changes to the Inpatient Prospective Payment Systems for Acute Care Hospitals and looks forward to working with CMS as it continues to implement these policies. Please contact Courtney Yohe, Director of Government Relations at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,



Keith S. Naunheim, MD
President
The Society of Thoracic Surgeons