The Society of Thoracic Surgeons

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Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-FC, P.O. Box 8013
Baltimore, MD 21244-8013.

Re: [CMS-5061-P] – Medicare Program:
Expanding Uses of Medicare Data by Qualified Entities

Dear Acting Administrator Slavitt:

The Society of Thoracic Surgeons (STS) appreciates the opportunity to submit comments on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities Proposed Rule (Proposed Rule). Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in 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 STS National Database (the Database), currently approved by the Centers for Medicare and Medicaid Services (CMS) as a Qualified Clinical Data Registry (QCDR), was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. 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 provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients. In fact, published studies indicate that the quality of care has improved as a result of research and feedback from the STS National Database.

The Database has facilitated advancements in many aspects of health care policy including public reporting of health care quality measures, facilitating medical technology approval and coverage decisions, and even saving money by helping cardiothoracic surgeons to find the most efficient and effective way to treat patients. Clinical data from the STS National Database has been linked with administrative claims data from CMS on a number of occasions either as a 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 offered new avenues for medical research. Clinical data yield sophisticated risk-adjustment assessments, while administrative data provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs.

We are very disappointed with CMS's decision not to adopt new policies or procedures to implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). Section 105(b) requires CMS to provide QCDRs with access to Medicare data for purposes of linking such data with clinical outcomes data and performing scientifically valid analysis or research to support quality improvement or patient safety. CMS decided not to issue a rulemaking on this section of the law based on its assertion that QCDRs can currently request Medicare claims data through the ResDAC data request process.

This position mistakenly assumes 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 was already available to them. CMS also ignores the fact that Section 105(b) is intended to provide QCDRs with access to Medicare data for quality improvement purposes, not just 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 will also dramatically increase the power of clinical outcomes data collected by QCDRs and therefore yield immeasurable benefits for patient health and safety. Lastly, CMS should match Medicare claims data with Social Security Death Masterfile (SSDMF) death data before providing it to QCDRs to greatly enhance the accuracy and robustness the Medicare claims data.

1. The Decision Not to Issue a Proposed Rule is Contrary to Congressional Intent

CMS is required to interpret a governing statute so as to give meaning and effect to the plain language of the law. It may not construe the statute in a manner that renders one or more provisions superfluous. CMS's decision not to issue a proposed rule implementing Section 105(b) violates these black letter principles of statutory construction.

Section 105(b) of MACRA specifically and unequivocally requires CMS to make Medicare claims data available to QCDRs so that they can link such data with the robust clinical information contained in registries like the STS National Database. STS and the Physician Clinical Registry Coalition, a group of more than 20 other physician-led clinical data registries, advocated for the inclusion of Section 105(b) in MACRA because patient outcomes information derived from the seamless combination of these data sources, when linked with Medicare claims data, creates a powerful tool for tracking patient outcomes over an extended period of time. The implications of such longitudinal studies for quality improvement are dramatic. Importantly, having access to Medicare claims data will also facilitate implementation of alternative payment models. By combining the STS National Database and claims information from Medicare and

other payors in a new alternative payment model structure, providers will be able to identify high impact areas for improvement based on quality or costs or both.

Congress enacted Section 105(b) with full understanding of the powerful synergies created when clinical outcomes data is married with administrative claims data. It knew full well that Medicare claims data was available to Qualified Entities and others, including QCDRs, through the ResDAC process. Yet, it still directed CMS to provide QCDRs with access to Medicare claims data for the purposes specified in the statute. If Congress were satisfied with fact that QCDRs could request claims data from ResDAC, it would not have included Section 105(b) in MACRA. Thus, CMS's decision not to issue new policies and procedures providing QCDR's with access to Medicare data beyond that currently available from ResDAC violates the clear intent behind Section 105(b) and longstanding rules of statutory construction.

2. CMS Must Provide QCDRs with Access to Medicare Claims Data for Quality Improvement Purposes, Not Just Research

Section 105(b) requires CMS to provide QCDRs with access to Medicare claims 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***." (Emphasis added.) Thus, the primary purpose of this section is to promote quality improvement, not research. This point is confirmed by the heading of the section: "Access to Medicare Claims Data by Qualified Clinical Data Registries to Facilitate Quality Improvement." CMS's statement in the Proposed Rule that "The CMS research data disclosure policies already allow qualified clinical data registries to request Medicare data for these purposes, ***as well other types of research***" (emphasis added) demonstrates the agency's misunderstanding of the purpose of Section 105(b) and the sharp distinction between research and quality improvement activities. This distinction is codified in the regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which clearly distinguish between research and quality improvement activities (a form of "health care operation") for purposes of protecting the privacy of patient identifiable information.

Moreover, Section 105(b) directs CMS to provide Medicare claims data to QCDRs for purposes of ***linking*** that data with clinical outcomes data. That language suggests that QCDRs must have broad and continuous access to large Medicare claims database, such as the 100% Medicare inpatient claims file, in order to conduct the probabilistic matching and linking process. As its name (Research Data Assistance Center) indicates, ResDAC provides Medicare claims data for discrete research projects. It requires applicants to submit proposals for such projects that identify specific cohorts of patients and specific protocols for conducting research studies on such cohorts. It then provides only the Medicare data necessary to perform that project. ResDAC also has a cumbersome application process that (a) does not guarantee access to data by an applicant, and (b) typically takes weeks and sometimes longer from application to approval.

By contrast, QCDRs require, and Congress intended to provide them with, timely and continuous access to large Medicare data sets to carry out the linking process and thereby enhance the power of their clinical outcomes databases to track patients over time, to capture all relevant procedures

or surgeries within a particular field or specialty, and to perform ongoing data aggregation services for their participants. Their needs are not limited to discrete research projects.

Congress' intent was that by virtue of meeting the requirements to become a QCDR, these registries would automatically be eligible for access to Medicare data for linking purposes. Requiring them to take their chances in the ResDAC process directly contravenes the purpose of Section 105(b). While there needs to be some mechanism for identifying and evaluating a QCDR's data linking needs, defaulting to the ResDAC research request process is not answer. CMS should be well aware of the fact that ResDAC is not the appropriate mechanism for meeting the objectives of Section 105(b). STS, the American College of Cardiology, and other established clinical data registries have linked their data with Medicare claims data on numerous occasions without going through ResDAC process. Rather, they have worked directly with CMS to obtain data from the 100% Medicare inpatient claims file and other databases not available through ResDAC.[1] Based on these experiences, CMS should know that it needs to establish a separate, more streamlined process that gives QCDRs timely access to broad Medicare data sets for purposes of linking such data with clinical outcomes data to support quality improvement activities.

3. The Secretary Should Match Medicare Claims Data with SSDMF Data Before Providing It to QCDRS

The Social Security Administration used to have a policy of sharing state-reported death data in the Social Security Death Master File (SSDMF) with third parties, including clinical data registries. This allowed for the verification of "life status" of patients who otherwise would be lost for follow up after their treatment. Unfortunately, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data so as to protect those listed in the file from identity theft. Balanced against legitimate privacy concerns are the many advantages of linked administrative and outcomes data when placed in the right hands, with adequate protections in place.

Fortunately, the Secretary of Health and Human Services has the authority under 42 U.S.C. § 405(r)(9) to match Medicare claims data with death data contained in the full SSDMF data file (not just the public SSDMF available to entities that meet certification criteria). Because the ultimate purpose for accessing death data was to enhance the accuracy of patient outcomes information, including verification of patient life status and date of death, and not the acquisition of the actual death data set itself, QCDRs would greatly benefit from the Secretary matching Medicare claims data with SSDMF death data to verify patient death status, and sharing the matched data set with QCDRs. This would be a permissible exercise of the Secretary's authority under 42 U.S.C. § 405(r)(9) and provide QCDR's with much more useful data for linking purposes.

[1] See, e.g., STS Successful Linking article.

Conclusion

The Proposed Rule's failure to include a new mechanism for providing QCDRs with timely and continuous access to Medicare claims data is clearly contrary to the congressional intent behind Section 105(b) of MACRA. The current ResDAC process is patently inadequate to provide QCDRs with the broad data sets necessary to allow them to meaningfully link their clinical outcomes data with Medicare claims data for quality improvement purposes. We therefore urge CMS to develop an appropriate data sharing mechanism that meets the intent of Section 105(b) and the data access and linking needs of QCDRs. We further urge CMS to commit to exercising the Secretary's authority to match Medicare claims data with SSDMF death data prior to providing such data to QCDRs.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Courtney Yohe at cyohe@sts.org or 202.787.1222.

Respectfully submitted,

Joseph E. Bavaria, MD
President