American Society of Transplant Surgeons

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September 6, 2013

Submitted Electronically: www.regulations.gov

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1600-P; RIN 0938-AR56; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014.

Dear Ms. Tavenner:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to submit these comments in response to the above-referenced *Federal Register* notice (the "Proposed Rule"). ASTS is a medical specialty society comprised of over 2000 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

These comments focus on CMS' proposed implementation of Section 601(b) of the American Taxpayer Relief Act of 2012 (ATRA), which allows eligible professionals to be treated as satisfactorily submitting data on quality measures for covered professional services if the eligible professional satisfactorily participates in a Qualified Clinical Data Registry (QCDR).

Background: Outcomes Reporting through the Scientific Registry of Transplant Recipients (SRTR).

Transplant surgeons participate in the Scientific Registry of Transplant Recipients (SRTR), a comprehensive national database of transplantation statistics. The SRTR operates under contract with the Health Resources and Services Administration, a sister agency to CMS within HHS. The SRTR transplant program reports include:

- Reliable transplant information for patients, families and medical professionals;
- A complete list of U.S. transplant centers;
- Waiting time and organ availability data; and
- Survival statistics.

The SRTR provides detailed patient and organ survival and other outcome information for every transplant for each transplant center and each type of organ transplant (i.e. kidney, liver, heart, heart-lung, pancreas, intestine, kidney-pancreas). This is precisely the type of specific, accessible outcome information that patients and prospective patients want *and* need. Each center's performance is risk adjusted and reported against applicable benchmarks: Actual performance is compared to "expected" performance on key measures, taking into account sophisticated (albeit as-yet-imperfect) risk adjustment methodologies.

Under the SRTR methodology, individual surgeon performance is not currently reported separately. This is as it should be. **Transplantation is a team activity and is dependent not only on individual surgeon performance but also on a myriad of other factors, including the quality of the services provided by the transplant center, organ procurement organization and other members of the transplant team, such as nurses, nutritionists, pharmacists, transplant coordinators, and administrators.** We invite you to explore the SRTR website at greater length at http://www.srtr.org/local_stats.aspx).

We firmly believe that the SRTR data collection process and the Program Specific Reports that it makes publicly available should serve as a model for other surgical procedures and that transplant surgeons that participate in the SRTR data collection process should be considered to be in compliance with PQRS and EHR incentive program requirements. The establishment of similar registries for other procedures can be best encouraged by approving the SRTR as a QCDR under Section 601(b) of ATRA and establishing clear criteria for other surgical registries to transition to similar outcome data collection and reporting in the future.

The Proposed Rule

CMS is required to establish requirements for an entity to be considered a QCDR, including a requirement that the entity provide information, at such time and in such manner, as CMS determines necessary. Under the statute, CMS must consider whether an entity:

- Has mechanisms for transparency of data, risk models, and measures;
- Requires submission of data with respect to multiple payers;
- Supports quality improvement initiatives; and
- Provides timely performance reports to participants at the individual level.

We believe that the provisions of the Proposed Rule implementing Section 601(b) of ATRA impose unnecessary burdens on a registry seeking to become a QCDR. Rather than setting forth prescriptive requirements for all aspects of registry operation, including data collection, sharing, IT requirements, auditing, and confidentiality, we urge CMS to limit the implementing regulations to those that set forth the basic process that CMS will use in determining whether a registry is eligible for "deemed status" but otherwise leaving clinical and operational matters in the hands of the registries themselves.

We are particularly concerned that, under the Proposed Rule, in order to be approved as a QCDR, a registry must provide access to the entire registry database or a copy of actual data. We believe that this requirement goes far beyond the type of "deeming" process that Congress had in mind in enacting the section 601(b) of ATRA. We are also concerned that CMS proposes to institute detailed requirements regarding the measures to be collected.[1] We strongly believe that this is precisely the type of prescriptive requirement that section 601(b) of ATRA was intended to eliminate. Rather than replicating PQRS reporting requirements in the QCDR criteria, we would urge CMS to enable registries to determine meaningful specialty-based measures, including outcomes measures of the type tracked by the Scientific Registry of Transplant Recipients.

Our primary concern, however, is that CMS proposes that the entity "demonstrate a plan to publicly report their quality data through a mechanism where the public and registry participants can view data about individual EPs, as well as regional and national benchmarks." While CMS only contemplates the participation of individual EPs, a QCDR should be able to fulfill the public reporting requirements by reporting on a group of EPs. As described at length above, SRTR does not report outcomes by individual EP but based on the transplant center. We believe that, for many specialties including transplant, obstetrics and trauma, reporting at the level of the clinical team acknowledges that healthcare delivery is an outcome of the actions of many individuals and the systems that support them.

We note that the governing legislation provides CMS with considerable discretion in fleshing out the requirements to be applied to registries that qualify as QCDRs and does not specifically require that individual surgeons' patient outcomes be publicly reported. Transplantation is truly a "team" endeavor, and outcomes depend on a myriad of physicians and surgeons and non-physician personnel and transplant recipients themselves. To attribute patient or organ survival solely to the lead transplant surgeon is to ignore the significant and often critical roles of the rest of the team. Such an approach would be inimical to the focus on care coordination that is the hallmark of quality assurance programs and that is increasingly recognized as critical by health care policymakers as more valid than individual performance.

Where, as is the case of in transplant surgery, an entire team is jointly responsible for patient outcomes, outcomes cannot be attributed to an individual physician and any effort to do so likely would create incentives for surgeons to engage in risk avoidance that is likely to reduce rather than improve the quality of care for transplant recipients. For these reasons, **we request CMS to modify the Proposed Rule to facilitate group reporting. If CMS believes that QCDRs to utilize group reporting would be inconsistent with the governing statute, we encourage CMS to pursue appropriate technical corrections to the governing legislation.**

QCDRs and the CQM Component of the Electronic Health Record Incentive Program

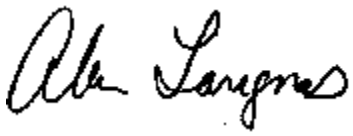
[1] CMS proposes to require QCDRs to report at least nine measures covering at least three of the NQS domains and to report each measure for at least 50 percent of the EP's eligible patients for a 12 month reporting period. For satisfactory reporting of quality measures under the QCDR reporting option, CMS proposes that the registry must report on a set of measures from one or more of the following categories: CG-CAHPS; NQF-endorsed measures, current PQRS measures; measures used by boards or specialty societies; and measures used in regional quality collaboratives.

Likewise, the SRTR data reporting system does not fit neatly into the rubric established under the CQM component of the EHR Incentive Program. In order to satisfy the CQM component of the EHR Incentive Program beginning in 2014, EPs must select and report nine CQMs covering at least three of the following six domains of quality of care: Patient and Family Engagement; (2) Patient Safety; (3) Care Coordination; (4) Population and Community Health; (5) Efficient Use of Healthcare Resources; and (6) Clinical Processes/Effectiveness EPs.

Transplant programs are very highly regulated both under the auspices of the Organ Procurement and Transplantation Network and by CMS through its transplant center conditions of participation. As the result of the regulatory requirements imposed by both the OPTN and CMS, transplant surgeons are integrally involved in patient and family engagement, patient safety, care coordination, population and community health (through efforts to increase organ retrieval and donation rates), efficient use of healthcare resources (including the organs themselves) and clinical processes of care**. In light of the substantial involvement of transplant surgeons in all of these arenas, we believe that transplant surgeons should be deemed to be in compliance with the CQM component of the Electronic Health Record Incentive Program.**

We appreciate the opportunity to comment on the Proposed Rule. If you have any questions, please do not hesitate to contact ASTS Executive Director, Kim Gifford, at *kim.gifford@asts.org* or 703-414-1609.

Sincerely,



Alan N. Langnas, D.O.
President