August 31, 2015

Administrator Slavitt
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Proposed Rule: CMS-1631-P: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Administrator Slavitt:

On behalf of the American Society of Transplant Surgeons (ASTS), we are pleased to have the opportunity to comment on the Physician Fee Schedule (PFS) Proposed Rule for 2016 (the Proposed Rule). ASTS is a medical specialty society composed of more than 1800 transplant surgeons, physicians, scientists, advanced transplant providers, and other transplant professionals dedicated to advancing the art and science of transplantation through leadership, advocacy, education, and training.

Our comments on the Proposed Rule are as follows:

- Liver transplantation (CPT 47135) is among the procedures addressed in the Proposed Rule as a “New, Revised, or Potentially Misvalued Code.” (See Tables 11 and 12 of the Proposed Rule.) While we continue to believe that the RUC proposed valuation more accurately reflects the work involved, we appreciate CMS’ proposal to increase the work RVUs associated with liver transplants and to accept the RUC direct expense proposed valuation.

- We appreciate CMS’ solicitation of the views of the affected groups regarding the methodology that should be used to collect the information on global period costs, as required by MACRA. In this regard ASTS supports the comments submitted by the American College of Surgeons (ACS) and urges that this process be used to gather the necessary information. We strongly support CMS’ decision to refrain from revaluing codes with 10 or 90 day global period under the misvalued code initiative pending this data collection and resolution of global surgery valuation issue.

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The Proposed Rule generally solicits input on implementation of MACRA’s Alternative Payment Model (APM) provisions, to help inform an upcoming Request for Information (RFI) to be published on this topic. In this regard, we note that MACRA defines alternative payment model to include a model instituted by the Centers for Medicare and Medicaid Innovation under Section 1115A, including the Bundled Payment for Care Improvement (BPCI) demonstration. In the Hospital Inpatient Prospective Payment System Proposed Rule for 2016, CMS solicited comments on expanding this demonstration and making it a permanent part of the Medicare Program.

A number of non-Medicare payers currently pay for transplant procedures and certain post-operative care management using a model comparable in many respects to Model 2 of the BPCI: Basically, payment is made for all professional, hospital, ancillary services and other health care services provided for a defined transplant episode of care. We encourage CMS to consider an expanded or permanent BPCI program to constitute an APM for the purposes of MACRA and to make this payment option available to transplant centers in time for participating transplant surgeons to be considered “qualified APM participant(s)” for PFS payment purposes in 2019.

Over the past year, ASTS has had a number of discussions with CMS about the possibility of gaining approval of the Scientific Registry of Transplant Recipients (SRTR)\(^1\) as a qualified clinical data registry (QCDR); however, ASTS placed these discussions on hold in light of MACRA’s repeal of PQRS in its current form. We believe that the time is now ripe to revisit the potential for SRTR to play a critical role in quality evaluation for transplant surgeons and other qualifying professionals under the Merit-based Incentive Payment System (MIPS) authorized by MACRA. In particular, we would like to re-institute consideration of SRTR either as a Qualified Clinical Data Registry for the purposes of MIPS quality measurement metrics or as a MIPS-approved “Clinical Practice Improvement Activity.”

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\(^1\) SRTR is a comprehensive national database of transplantation outcomes and other information. 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 for each center; and
- Patient and organ 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). 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.

This information, which is made public, is precisely the type of specific, accessible outcome information that patients and prospective patients want and need.
SRTR as a QCDR for the purposes of the Quality and Value Components of MIPS. A number of provisions of MACRA support the approval of the SRTR as a factor to be considered in determining transplant surgeons’ MIPS scores. For example, MACRA includes provisions facilitating the use of “virtual groups” for the purposes of fulfilling the quality and value component of MIPS. Under these provisions, the performance of each individual in the virtual group is based on the virtual group’s performance; therefore, all of the MIPS participants in a virtual group will have the same quality and value “scores” for the purpose of MIPS. Thus, it appears that the legislation addresses one of the primary roadblocks involved in approval of SRTR as a QCDR by eliminating the current requirement for PQRS performance to be determined on an individual basis—a feature of the current system that is inimical to the “team approach” used in transplantation.

In addition, a number of provisions of MACRA are consistent with the approval of the SRTR as a QCDR for MIPS purposes. For example, MACRA:

- Specifically directs CMS to emphasize outcomes measures in formulating the quality component of MIPS (“In applying [the quality component of MIPS], the Secretary shall, as feasible, emphasize the application of outcome measures.”).
- Directs CMS to use QCDRs to the extent practicable under MIPS (“USE OF REGISTRIES.—Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection.”).
- Authorizes CMS to use hospital measures in determining physician scores under the quality component of MIPS. (“APPLICATION OF ADDITIONAL SYSTEM MEASURES.—The Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the performance categories described in [the quality and value components of MIPS”].
- Specifically authorizes the use of global and population-based measures under the quality component of MIPS. (“(iii) GLOBAL AND POPULATION-BASED MEASURES.—The Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the [quality] performance category for MIPS.”)

MACRA includes a number of provisions related to the solicitation of quality measures to be used under MIPS, and ASTS looks forward to participating in this regulatory process.

SRTR as a Clinical Practice Improvement Activity. MACRA defines Clinical Practice Improvement Activity as:

an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.
For MIPS purposes, clinical practice improvement activities must include population management (such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry), and patient safety and practice assessment such as through practice assessments related to maintaining certification. SRTR serves both population health and practice assessment objectives, and we believe that participation constitutes precisely the type of activity that should be considered a clinical practice improvement activity for MIPS purposes.

ASTS appreciates the opportunity to comment on the Proposed Rule, and looks forward to meeting with CMS to ensure that MACRA is implemented in a manner that provides transplant surgeons with robust opportunities to participate in future rulemaking surrounding implementation of MACRA. Please contact ASTS Executive Director Kimberly Gifford at kim.gifford@asts.org or 703-414-7870 to arrange this important meeting.

Sincerely yours,

Charles M. Miller, MD
President