ASTS
American Society of Transplant Surgeons

September 1, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, CMS-1654-P

Dear Acting Administrator Slavitt:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have this opportunity to comment on the 2017 Physician Fee Schedule Proposed Rule ("the Proposed Rule"). The American Society of Transplant Surgeons represents more than 1,600 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

ASTS is extremely concerned about CMS' proposed methodology for collecting data on the services included in global surgery codes. The first prong of the proposed data collection methodology would require all surgeons who perform any 10- or 90-day global services to include newly created non-payable "G" codes on their claims. We strongly believe that, for the reasons set forth at length in the comments filed by the American College of Surgeons (which are incorporated here by reference), such a data collection process imposes an extraordinary administrative burden on all surgeons and that it is inconsistent with a plain reading of The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

This claims-based data collection method is inconsistent with MACRA for several reasons. MACRA requires data collection to be based on a representative sample of physicians, while the proposed data collection methodology set forth in the Proposed Rule would collect data from all practitioners who furnish 10- and 90-day global services. Since the legislation only contemplates collection of data from a sample of surgeons, and collection of data on all surgical services would be virtually impossible based on a reasonably sized sample, the legislation impliedly suggests that data should be collected on some, but not all surgical procedures with 10- and 90- day global periods. This more limited data collection—with data collected from

only a representative sample of surgeons and for selected surgical services—is consistent with the stated purpose of the survey as set forth in MACRA: Section 1848(c)(8)(C) of the Act states that the data collected is "*for the purpose of improving the accuracy of valuation of surgical services under the physician fee schedule under this section.*"

By contrast, the claims based data collection described in the Proposed Rule suggests that CMS is seeking data to be incorporated directly into revaluations of global surgical procedures, potentially using a formulaic approach.This is a far more extensive undertaking, and one that is not contemplated by MACRA.

Moreover, as currently proposed, this method of collecting data is virtually guaranteed to yield distorted results, and, in particular, to underreporting of the services provided by surgeons during the global period. For all the reasons set forth in the comments filed by the American College of Surgeons, the time-based "G" codes that CMS proposes to create for the purposes of the survey are not workable and bear no relationship to surgeons' work flow; utilize unfamiliar and ambiguous descriptors; and are extremely unlikely to be reported consistently or reliably. Any effort to move forward with implementation of data collection utilizing these codes is extremely likely to yield unusable results, but only after considerable expenditure of time and effort both by CMS and by the surgical community.

While transplant surgeons share the concerns described by others with respect to this first "prong" of CMS' proposed data collection methodology, a number of the challenges that this proposal would pose are unique to transplant surgeons. Transplantation is truly a "team" endeavor, and outcomes depend on the concerted efforts of a myriad of physicians and surgeons and non-physician personnel, including not only the transplant surgeon, but also assistant surgeons, the Organ Procurement Organization, the organ retrieval team, the transplant physician, the transplant program clinical coordinator, transplant nurses, nutritionists, pharmacists, family members, and transplant recipients themselves. Patient and organ survival is not attributable to the activities of any single member of the team, and the concerted and seamless integration of the activities of all team members is critical to achieving the most positive outcomes. Care coordination is the hallmark of transplant center quality assurance programs and, accordingly, Medicare's transplant center certification regulations themselves strongly emphasize the need for a fully operational and integrated transplant "team." See, e.g., 42 CFR §482.94(a) requiring that each transplant recipient and living donor be under the care of a multi-disciplinary team; 42 CFR §482.94(c)(3), requiring multidisciplinary involvement in discharge planning and throughout transplant period.

Surgeons in the practice other than the one who performed the transplant may care for patients while inpatient or outpatient—including lab reviews, review of immunosuppression, etc.—and it will be extraordinarily difficult, if not impossible, to capture accurate data for each surgeon-patient encounter. Furthermore, pre- and post-transplant work includes care coordination with other specialties—nephrology, hepatology, infectious diseases, etc.—and this occurs at all times of the day and night, adding another layer of complexity to accurate data capture.

CMS' proposal to collect data based on time-based "G" codes (measured in 10 minute increments) that are reportable only for face-to-face services is inimical to the concept of team-based transplant surgery. Clinical practices vary substantially regarding which members of a team will provide the services

reportable using the proposed inpatient "G" codes: In some institutions and practices, the inpatient visit may be conducted by the primary surgeon and in other institutions and practices, efficiency and quality may dictate that other team members perform at least some of these services. Due to this variability, the use of the "G" codes to collect data on the scope and intensity of the services performed by the principal surgeon during the inpatient stay is likely to yield internally inconsistent and undecipherable data.

Moreover, the definitions of "routine", "complex," and "critical" visits described in the Proposed Rule are not particularly useful in the context of transplant surgery. As we understand it, a visit that does not go beyond the tasks set forth in Table 10 would be reported as a "routine" inpatient visit (GXXX1). [1] While an inpatient hospital visit to a post-transplant patient may not go beyond the tasks set forth in the Table, the complexity of those tasks is substantially greater than for similar tasks performed for a patient who has undergone straightforward elective surgery. The complexity levels for the post-operative inpatient visits simply do not reflect clinical complexity, which is more accurately defined by the E/M codes with which the physician community is already familiar.

The "office or other outpatient" "G" codes proposed by CMS raise similar issues. Transplant patients sometimes travel substantial distances to receive a transplant, and sometimes come from the local area. The physician who will provide face-to-face outpatient visits during the post-operative period may vary, depending on the patient's circumstances, and therefore it is unlikely that CMS will obtain reliable and consistent data on the frequency and intensity of post-discharge post-operative visits using claims based data. In addition, the same objections to the proposed complexity levels that are set forth above with regard to inpatient post-operative visits apply equally to visits conducted after the patient is discharged. Finally, many transplant centers are also teaching hospitals, and residents often perform a critical role in the provision of care to transplant recipients and donors, both during the hospital stay and during the 90-day post-discharge period. Transplant patients present unique clinical challenges, especially with respect to immunosuppression, and caring for these patients requires specialized knowledge and training. As a general rule, then, the care of transplant patients post-operatively is handled exclusively by trained transplant surgeons and residents, and does not involve critical care specialists and intensivists, whose services may be billed separately. For the purposes of data collection, the services provided by residents should be considered as if they were performed by the primary transplant surgeon, since, in the absence of resident coverage, they would in fact be performed by the primary transplant surgeon.

[1] These tasks include:

- Review vitals, laboratory or pathology results, imaging, progress notes
- Take interim patient history and evaluate post-operative progress
- Assess bowel function
- Conduct patient examination with a specific focus on incisions and wounds, post-surgical pain,
- complications, fluid and diet intake
- Manage medications (for example, wean pain medications)
- Remove stitches, sutures, and staples
- Change dressings
- Counsel patient and family in person or via phone
- Write progress notes, post-operative orders, prescriptions, and discharge summary
- Contact/coordinate care with referring physician or other clinical staff
- Complete forms or other paperwork

For these reasons, we urge CMS to abandon its proposal to use claims data collected for all services and from all physicians to determine the complexity and frequency of services provided during the global period, and to work closely with the American College of Surgeons to determine an alternative methodology based on data collected from a "representative sample" of surgeons. In addition, the team-based nature of transplant surgery and the variations in practice patterns for patients discharged to distant locations present a number of unique features. We would be delighted to work with you to devise a methodology for collecting data on the services included in the 90-day global period for transplant donors and recipients, in light of these unique features of these highly complex, team-based and critical procedures.

Sincerely yours,

Timothy L. Pruett, MD
ASTS President