



American Society of Transplant Surgeons

September 2, 2014

Submitted electronically at www.regulations.gov

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

Dear Ms. Tavenner:

On behalf of the American Society of Transplant Surgeons (ASTS), we appreciate the opportunity to submit comments to the 2015 Physician Fee Schedule Proposed Rule (the "Proposed Rule"). ASTS is a medical specialty society composed of over 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 address:

- **Valuation and Coding of the 10- and 90-day Global Surgical Package**
- **CMS' proposal to provide notice and an opportunity for comment before implementation of payment rates for new, revised, and potentially misvalued services.**
- **Proposed Revisions of Sunshine Act Reporting Requirements for Accredited Continuing Medical Education (CME) activities**
- **CMS proposed implementation of new requirements for reporting using a Qualified Clinical Data Registry (QCDR)**

National Office
2461 South Clark Street
Suite 640
Arlington, VA 22202
Phone: 703 414-7870
Fax: 703 414-7874
asts@asts.org
www.ASTS.org

President

Peter G. Stock, MD, PhD
University of California-San Francisco
505 Parnassus
San Francisco, CA 94143
Phone: 415-353-1551
Fax: 415-353-8974
peter.stock@ucsfmedctr.org

President-Elect

Charles M. Miller, MD
Cleveland Clinic Foundation
9500 Euclid Ave.
Mail Code A-110
Cleveland, OH 44195
Phone: 216-445-2381
Fax: 216-444-9375
millerc8@ccf.org

Secretary

Dixon B. Kaufman, MD, PhD
University of Wisconsin
600 Highland Ave
H5/701 Clinical Science Center
Madison, WI 53792-7375
kaufman@surgery.wisc.edu

Treasurer

Timothy L. Pruett, MD
University of Minnesota
Department of Surgery
420 Delaware Street
SE MMC 195
Minneapolis, MN 55455
tlpruett@umn.edu

Immediate Past President

Alan N. Langnas, DO

Past President

Kim M. Olthoff, MD

Councilors-at-Large

Jean C. Emond, MD
Abhinav Humar, MD
Lloyd E. Ratner, MD, MPH
Douglas G. Farmer, MD
James F. Markmann, MD, PhD
Mark D. Stegall, MD
Ginny L. Bumgardner, MD, PhD
Kenneth D. Chavin, MD, PhD
A. Osama Gaber, MD

Executive Director

Kimberly A. Gifford, MBA
Kim.gifford@asts.org

Each of these issues is addressed below.

I. Valuation and Coding of Global Surgical Packages

CMS proposes to transition all 10- and 90-day global surgical codes to 0-day global surgical codes by 2017 and 2018, respectively. Under this policy, medically reasonable and necessary pre- and post-operative visits would be separately billable. This significant proposed revision of longstanding Medicare policy is based in large measure on CMS' concerns about whether the post-operative services included in the current valuations are actually provided.

ASTS Position: The ASTS supports, and incorporates by reference, the comments of the American College of Surgeons (ACS) on this issue. We strongly urge CMS not to finalize this proposal without comprehensive analysis of its impact on patients, providers, and program administration. While we understand that CMS has concerns about the accuracy of the data upon which current valuations are based, we continue to believe that the RUC is currently in the best position to evaluate post-operative work and, unless and until new and potentially more reliable sources are identified and vetted, the current valuation methodology should not be changed. And even assuming (without conceding) that estimates of the post-operative visits might be improved, this argues for refinement of—rather than elimination of—the global periods. Global surgery codes continue to make sense, especially in the case of transplant surgery: Compared to earlier eras, transplant surgical patients today are more often on anti-platelet or anti-coagulation medications prior to transplantation and unlike patients undergoing elective surgery, many transplant recipients cannot have those medications managed pre-transplant because of the immediacy of transplant surgery with deceased donor organs. This requires more peri-operative care and use of lines, drains and tubes to manage bleeding and fluid collections post-transplant. In addition, transplant recipients have the added complexity of a higher risk of infection, requiring a high degree of post-surgical wound care and other peri-operative cares to minimize infectious complications. We are concerned that these factors – and similar considerations that may apply in the case of other types of specialized surgery – are not considered in CMS' proposal. In fact, CMS proposes eliminating the global periods without clearly identifying an alternative methodology with sufficient specificity to enable affected providers to model the impact of the proposed change(s) on their practices and patients. For these reasons, as well as those articulated by the ACS in its comprehensive comments on this issue, we strongly urge CMS to refrain from finalizing this proposal.

II. Valuing New, Revised, and Potentially Misvalued Codes

Under the current process, CMS issues interim final RVUs for all revaluations and new codes in the PFS final rule each November, without providing notice or an opportunity to comment prior

to implementation of new (or revised) payment rates. CMS proposes to improve the transparency of the process by including proposed RVU changes in the proposed rule for codes in which CMS receives RUC recommendations in time, and continue to establish interim final values in the final rule for other new, revised or potentially misvalued codes.

ASTS Position: We strongly support CMS' proposal to provide notice and an opportunity for comment with respect to new and revised RVUs for new, revised and potentially misvalued codes. This proposal represents a significant improvement over the current process, and we commend CMS for taking this step toward increased transparency. We urge CMS to work with the RUC to work out issues related to the deadlines for RUC recommendations, in an effort to minimize the use of G-codes to the extent possible. We also urge CMS to retain the Refinement Panel process, which enables focused review of changes in Medicare payment.

III. Proposed Revisions of Sunshine Act Reporting Requirements for Accredited Continuing Medical Education (CME) activities

The regulations implementing the Sunshine Act currently include a provision that excludes from reporting payments made by manufacturers and others to physicians serving as speakers at accredited continuing medical education (CME) programs. See 42 CFR Section 403.904(g)(1). CMS is proposing to eliminate this exclusion on the grounds that such support is already excluded from reporting under another provision of the Sunshine Act regulations—the provision that excludes from reporting: “indirect payments or other transfers of value where the applicable manufacturer is ‘unaware of’...the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.”¹ CMS states that physicians speaking at CME programs would fall under this exception.

*ASTS Position: ASTS **opposes** the elimination of the CME exclusion and believes that commercial support to an accredited CME provider, which may be used to pay physician speaker fees, should be exempt from reporting requirements. As an accredited CME provider, ASTS must adhere to the ACCME Standards of Commercial Support and other policies to ensure complete separation between promotion and education. We are concerned that finalizing the Proposed Rule as currently written would seriously impact our ability to get the best speakers (or any speakers) for our educational programs. We do not believe that the exclusion for indirect payments provides a clear or adequate substitute for the CME exclusion: Since manufacturers typically do know the identity of speakers at CME programs during the time period identified in the “indirect payment” exception, that exception likely will not apply in many cases. If CMS intends to make this*

¹ "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule." Federal Register 79 (11 July 2014): 40384. Online.

exception available for manufacturer support of accredited CME programs, we strongly urge CMS to amend the regulatory text to specifically state that a manufacturer will be considered unaware of the identity of the covered recipient if the manufacturer does not know the identity of the speaker(s) at the time the support is provided.

IV. Proposed Changes Related to Qualified Clinical Data Registries (QCDRs)

In the Proposed Rule, CMS proposes to defer to the QCDR to determine whether to report performance results on the individual EP level or to aggregate the results of EPs who are in the same practice together.

ASTS Position: ASTS strongly supports this proposal. We strongly believe that CMS should permit a group level QCDR reporting option. As we have pointed out in prior comments, the relevant clinical outcomes of transplant programs, including graft and patient survival, are already collected by the Scientific Registry of Transplant Recipients (SRTR) and publicly reported on an easily accessible and user friendly website. We urge CMS to utilize the SRTR model in fashioning requirements for QCDRs, especially those related to surgery, and to refrain from so burdening the QCDR approval process with administrative and other requirements as to discourage the formation of similar registries in other fields. We would be delighted to meet with you to discuss this concept in further detail.

V. Other Quality Issues

In addition, ASTS would appreciate CMS' consideration of the following additional comments and observations:

- ASTS strongly urges the inclusion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey measure (S-CAHPS). ASTS is currently working with the ACS and others on the development of a consumer survey that is specifically geared to the special concerns and needs of transplant surgeons.
- CMS proposes the elimination of a number of surgery related measures from the existing PQRS set beginning in 2015.² In light of the dearth of measures reportable by surgeons, and the penalties that accompany failure to report both under PQRS and under the Value Modifier (VM) program, ASTS urges CMS to refrain from eliminating any surgical measures at this time.
- ASTS strongly urges CMS to refrain from increasing the penalty under the VM program from -2.0 percent to -4.0 percent for those groups and individual EPs who do not meet

² PQRS #21: Perioperative care: selection of prophylactic antibiotic-first or second generation cephalosporin; PQRS #22: Perioperative care: discontinuation of prophylactic parenteral antibiotics; PQRS #23: Perioperative care: venous thromboembolism prophylaxis when indicated in all patients

the criteria for satisfactory PQRS reporting and for those groups and solo practitioners classified as low quality/high cost. ASTS strongly urges CMS not to implement this proposal, especially in light of the paucity of measures reportable by surgeons. In addition, we believe that it would be patently unfair to subject so large a proportion of physician payment to potential reduction in light of the current lack of an established and fully tested process to implement corrections to the VM data. While we understand that an informal process for correcting VM data is proposed (and we fully support this proposal), we believe that increasing the potential VM penalty to 4% in the absence of a fully implemented process is not appropriate.

We appreciate the opportunity to comment on this proposed rule. If you have any questions regarding ASTS' position with regard to the Proposed Rule, please do not hesitate to contact Kim Gifford, ASTS Executive Director, at kim.gifford@asts.org.

Sincerely yours,

A handwritten signature in cursive script that reads "Peter G. Stock".

Peter G. Stock, MD, PhD
President