



American Society of Transplant Surgeons

June 9, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1655–P. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates (Proposed Rule).

Dear Mr. Slavitt:

On behalf of the American Society of Transplant Surgeons (ASTS), I am writing to you with regard to certain changes to hospital inpatient quality measures set forth in the Proposed Rule. ASTS is a medical specialty society representing more than 1,500 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.

The Proposed Rule proposes an updated version of the PSI 90 composite measure in the HAC Reduction Program, Hospital Inpatient Quality Reporting Program and the Hospital Value Based Purchasing Program. CMS proposes the following changes to the measure:

- *The name of the PSI 90 measure has changed to “Patient Safety and Adverse Events Composite” (NQF #0531) (referred to as the “modified PSI 90”);*
- *The modified PSI 90 measure includes the addition of three indicators:*
 - *PSI 09 Perioperative Hemorrhage or Hematoma Rate;*
 - *PSI 10 Physiologic and Metabolic Derangement Rate;*
and
 - *PSI 11 Postoperative Respiratory Failure Rate;*
- *PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate and PSI 15 Accidental Puncture or Laceration Rate have been re-specified;*
- *PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90; and*
- *The weighting of component indicators in the modified PSI 90 is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events.*

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

President
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

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

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
Lloyd E. Ratner, MD, MPH
Columbia University
Department of Surgery
622 West 168th Street
New York, NY 10032
lr2182@columbia.edu

Immediate Past President
Peter G. Stock, MD, PhD

Past President
Alan N. Langnas, DO

Councilors-at-Large
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
William C. Chapman, MD
Carlos O. Esquivel, MD, PhD
Dorry L. Segev, MD, PhD

Executive Director
Kimberly A. Gifford, MBA
kim.gifford@asts.org

The proposed changes inappropriately fail to take into account the unique clinical considerations involved in the provision of transplant surgery. We have reviewed the numerator/denominator/exclusion criteria and believe that PSI09-PSI12, as modified, would pose real threats to the appropriate evaluation of quality of care for those hospitals that operate transplant centers. As set forth below, the proposed modifications of PSI09 fail to take into account critical clinical considerations for all transplant surgery; the proposed modifications of PSI10 are inappropriate in the context of liver transplantation; and the proposed modifications of PSI11 and PSI12 are inappropriate in the context of both liver and kidney transplantation. Each of these is set forth below.

We also note that the risk adjustment methodology used for the hospital quality measures is not specific to, or necessarily germane to, transplantation. Specifically there is no adjustment for severity of illness at time of transplant (by a transplant-specific measure, such as Model for End-stage Liver Disease (MELD)), and there is no adjustment for deceased donor characteristics which have an enormous impact on the PSI measures cited (perioperative hemorrhage, acute renal failure, prolonged intubation). For these reasons, we believe that it is especially important that the exclusions described below be included in determining hospital performance under these measures.

PSI09: perioperative hemorrhage or hematoma

Perioperative hemorrhage or hematoma is the norm after liver transplant, and is frequent after kidney transplant, and the repercussions of these and other transplantation procedures are NOT indicative of poor quality care. While this measure excludes cases with any listed ICD-9-CM diagnosis codes for coagulation disorder and this code may apply to many transplant patients, we strongly believe that, since perioperative hemorrhage or hematoma is frequent for virtually all transplant procedures and is not indicative of quality concerns, transplantation should be added to the exclusion list *a priori*.

PSI10: acute renal failure

This measure is inappropriate for liver transplantation: While the measure excludes patients with pre-operative renal failure, many liver transplant patients with relatively normal baseline renal function get Acute Renal Failure after transplant despite high quality care, due to hemodynamic factors and the nature of the drugs involved in the performance of the procedure and its aftermath. For this reason, we request that liver transplantation be added to the exclusion list *a priori*.

PSI11: acute respiratory failure or mechanical ventilation for 96 consecutive hours or more or mechanical ventilation for less than 96 consecutive hours that occurs two or more days after the first major operating room procedure or reintubation that occurs one or more days after the first major operating room procedure

Despite high quality care, transplants have high incidences of acute respiratory failure, mechanical ventilation, and reintubation meeting the specifications set forth in this measure, due to the fluid shifts, medication, neurological status, and potential for infection involved in this complex surgery. While more common in liver than in kidney transplantation, acute respiratory failure, mechanical ventilation, and reintubation are fairly common for both procedures, and do not suggest or imply poor quality care.

For these reasons, liver and kidney transplantation should be added to the exclusion list for this measure.

PSI12: deep vein thrombosis

Changes in coagulation in the early postoperative period may lead to increased incidence of clotting disorders including DVT after transplant procedures. Deep Vein Thrombosis (DVT) also may be caused by large bore IVs. In addition, transplant patients often get products that promote clotting due to inherent coagulopathy, and some patients have clotting disorders that cause hypercoagulability. Please note that this measure excludes surgeries involving interruption of the vena cava, and all liver transplants involve such interruption. In addition, some kidney transplants involve such interruption of iliac veins and thus would be excluded from this measure if iliac veins are considered vena cava; however, because of the frequency of DVT in transplantation and because DVT is not indicative of poor quality care for these procedures, we request that liver and kidney transplant be added to the exclusion list.

Unless these changes are made to the quality measures as set forth above, we believe that the proposed revisions of these measures as set forth in the Proposed Rule have the potential to significantly distort the quality measurement of medical centers that operate transplant centers.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Miller', with a long horizontal flourish extending to the right.

Charles M. Miller, MD
President
American Society of Transplant Surgeons