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June 11, 2008

Kerry Weems
Administrator
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Attention: CMS-1390-P
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Submitted via the CMS public comment website: http://www.regulations.gov

Re: **FY 2009 Inpatient Prospective Payment Proposed Rule; File Code CMS-1390-P**

Dear Mr. Weems:

The American Society of Transplant Surgeons (ASTS) is pleased to have this opportunity to comment on the proposed inpatient prospective payment rule for FY 2009. ASTS is an organization comprised of over 1000 transplant surgeons, physicians and scientists dedicated to excellence in transplantation 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.

I. Hospital Acquired Conditions

ASTS fully supports the agency's goal of improving quality of care through the implementation of evidence-based clinical guidelines. However, we are concerned that several of the proposed hospital-acquired conditions do not meet the statutory requirement of being "reasonably preventable" with the use of evidence-based clinical guidelines, particularly when applied to immune-compromised transplant patients. The HACs of particular concern are (1) ventilator-associated pneumonia (VAP); (2) staphylococcus aureus septicemia; (3) *Clostridium difficile* Associated Disease (CDAD); and (4) delirium.

The first three, which relate to infection prevention, are extremely problematic for transplant patients who are immune-suppressed either as a result of their underlying organ failure disease or as a result of immunosuppressive therapy necessary to prevent rejection of the graft organ. To be reasonably preventable there should be strong evidence in the peer-reviewed literature that implementation of specific guidelines can eliminate or substantially eliminate the occurrence of an event in a specific patient population. We do not believe such evidence exists for transplant patients.

Literature cited in the Federal register on VAP indicates that there is evidence that routine infection control measures can *reduce* the risk of VAP. However, this is not the same as eliminating most or all cases and nowhere in the literature is there a suggestion that VAP is completely preventable. In fact the references cited in the Federal Register (AARC www.rcjournal.com/cpgs/09.03.0869) indicate that the evidence for various measures applied to ventilator care reduce risk for VAP in the range of 20-50%. This means that even with the use of evidence-based guidelines, there will still be a substantial number of patients who will develop VAP. More importantly, none of the studies cited stratified infection risk by immunosuppressive state, and there is no level 1 or 2 evidence supporting the effectiveness of any measures in reducing the risk of VAP in transplant patients. This is particularly true for liver, heart or lung transplant candidates or other transplant recipients. Many come from outside hospitals already intubated and suffering from multiple organ failure. Thus, they arrive at the hospital already immune-compromised and are routinely immune-suppressed intentionally after transplantation to prevent rejection of the transplanted organ.

Similarly, with respect to staph aureus septicemia, the literature supports reduction in incidence through the use of various infection control measures but does not establish that the incidence can be reduced to zero or near zero. Moreover, there are no studies that measure prevention in immune-compromised patients.

CDAD, in particular, is often very difficult to prevent in transplant patients, especially those receiving liver transplants who often have been on long-term antibiotics prior to transplant and who receive antibiotics post-transplant to prevent post-operative infections. Many such patients are already infected before they come to the hospital for their transplant. Medically necessary antibiotic therapy combined with the fact that such patients are often already colonized and immune-suppressed, makes prevention of CDAD extremely problematic even if all appropriate measures are followed.

It is important to understand that patients with liver or renal insufficiency who are admitted for liver or kidney transplants have been shown to be endogenously immune-compromised before any anti-rejection medications are administered. Therefore, these patients are often colonized or overtly infected at the time of admission. It may be very difficult to establish that these conditions were present on admission (POA) especially given the very short time frame that often exists between admission and transplant. Thus, despite institution of the most stringent anti-infection measures, infections in these patients are not "reasonably preventable" through the usual prophylactic measures.

We are also concerned about the proposal to include delirium on the HAC list. Many transplant recipients, particularly liver transplant recipients, have a complex metabolic encephalopathy post-transplantation due to a number of factors, including their pre-operative condition. Some

medications (e.g. calcineurin inhibitors and steroids) can induce and/or aggravate this condition, resulting in "delirium." However, use of these medications is necessary to prevent rejection of the transplanted organ. Including delirium as an HAC could penalize hospitals for administration of medically appropriate care.

We are also very concerned that CMS refers to these conditions as "never events." This creates confusion especially for patients and their families since it suggests that these conditions must be the result of poor quality of care even though it is inevitable that some patients will develop these conditions even with strict adherence to clinical guidelines.

In summary, ASTS supports CMS' efforts to improve quality of care through the broadest possible implementation of evidence-based guidelines. However, we do not believe the HACs discussed above should be implemented at this time because they do not meet the statutory criterion of being "reasonably preventable" through use of evidence-based guidelines. Moreover, if and when these HACs are implemented, they should not be applied to patients who are immune-compromised.

II. DRG Weights for Heart and Liver Transplants

ASTS is extremely concerned about proposed reductions in the MS-DRG weights for heart transplants and liver transplants without a major complicating condition (MCC). The MS-DRG weight for a liver transplant without an MCC (MS-DRG 6) would decrease by approximately 33% and the MS-DRG weight for a heart transplant without an MCC (MS-DRG 2) would be reduced by 20%. At the same time, there is only a nominal increase (approximately 1.2%) in the weights for the heart and liver transplant MS-DRGs with an MCC. We are not aware of any clinical advances in care which could conceivably account for such significant reductions in hospital costs. Nor are there any significant reductions in length of stay associated with these DRGs that might explain these substantial decreases. Fluctuations of this amount in any given year are extremely destabilizing to transplant center financial operations. Year to year shifts of such extreme proportions make financial planning and the maintenance of high quality transplant programs very problematic. Moreover, this comes at a time when transplant centers are faced with significant additional costs related to complying with new Medicare conditions of participation.

We also note that there are significantly more cases with MCC than without MCC in both the liver and heart transplant MS-DRG family. Based on available 2007 MedPAR data, only 30%of the heart transplant cases (287) were "without MCC" and only 26% of the liver transplant cases (229) were assigned to the "without MCC" MS-DRG. Data from the previous year suggest that the trend is clearly in this direction and we believe the number of cases in the "without MCC" MS-DRGs will continue to become proportionately less. Given this skewed distribution of cases and the relatively low number of cases in the "without MCC" MS-DRGs, we question the logic of maintaining separate MS-DRGs for liver and heart transplants. This lop-sided distribution of cases combined with the need to maintain budget neutrality within the DRG family yields DRG weights for "without MCC" cases that are disproportionately low and fail to adequately reimburse hospitals for their costs.

Given the above, ASTS urges that CMS reconsider the appropriateness of the current MS-DRG structure for heart and liver transplants. In this regard, we would like to renew the objections we

raised to this last year when CMS first proposed the creation of two MS-DRGs for heart and liver transplants and to ask that CMS establish a single MS-DRG for heart transplants and a single MS-DRG for liver transplants.

At the very least, we ask that CMS carefully review for accuracy the data used to establish the proposed DRG weights for the non-MCC heart and liver transplants for FY 2009. The significant reductions from one year to the next cause us to question the statistical reliability of the data used.

A. Impact on Medicare-approved Transplant Centers

When CMS proposed the current MS-DRGs in 2007, ASTS obtained the services of a consultant to review the impact of the new MS-DRGs for liver and heart transplants on Medicare-approved transplant centers. Based on the consultant's analysis, over 50% of heart and liver transplant centers reviewed would experience a reduction in DRG reimbursement for heart or liver transplants. What is more alarming, however, is that of the 52 liver transplant centers for whom data was available, 11 (19%) would undergo reductions of more than 10 percent, with many experiencing reductions of over 20%. Of the 37 heart transplant centers for which data was available, 10 (27%) would undergo DRG payment reductions of more than 10 percent.[1] We are very concerned that reductions of this magnitude would result in significant economic instability at these centers and may even cause some programs to close. This would be extremely disruptive to patients on the waiting list at those centers.

Moreover, as is evident in the FY 2009 proposed rule, the low volume of these procedures makes these DRGs very vulnerable to fluctuations. Splitting these already low volume procedures into two separate DRGs compounds this effect.

B. Proposed Weights for Procedures without an MCC are Too Low

Although we understand that, in developing the MS-DRG weights, CMS has attempted to achieve budget neutrality within each DRG family, ASTS remains very concerned about the proposed reimbursement for heart and liver transplants that would be assigned to the DRGs without an MCC. As noted in the table below the weights for the non-MCC DRGs are extremely low – less than half the weight assigned to the "with MCC" procedures for liver transplants and about half in the case of heart transplants. Moreover, they would drop significantly even below the already low 2008 amounts.

DRG	Description	Current Weight – FY 2008	Proposed Weight for FY 2009
MS DRG1	Heart Tx w/MCC	23.1117	23.4061
MS-DRG 2	Heart Tx w/o MCC	16.2735	12.8956
MS-DRG 5	Liver Tx w/MCC	10.6120	10.7436
MS-DRG 6	Liver Tx w/o MCC	7.2562	4.8292

[1] Because of patient privacy rules, the consultant was unable to provide an analysis of transplant centers performing fewer than 10 Medicare transplants; consequently many of the small transplant centers are not included in this analysis.

We estimate that the average payment under DRG 6, a "low complexity" liver transplant with an average LOS of 10.25 days would be $24,623. We do not believe there are many, if any, transplant centers that could perform a liver transplant for this amount, even if the LOS was 4 or 5 days.

Similarly, payment under DRG 2 for a "low complexity" heart transplant with an average LOS of 24.75 days would be approximately $63,897. Again, ASTS is not aware of any heart transplant centers that could perform a heart transplant for this amount.

We do not believe that the DRG weights for the heart and liver MS-DRGs appropriately reflect the costs of these procedures and, with respect to the "low complexity" procedures, we are concerned that this may create incentives to turn away patients without MCCs or lead to inappropriate upcoding.

C. The MS-DRGs for heart and liver transplants do not take into consideration the most significant factors affecting costs of transplant procedures.

As ASTS noted in its 2007 comments on the proposal to establish MS-DRGs for heart and liver transplants, the presence or absence of a condition on the MCC list is not a good predictor of inpatient hospital costs for liver and heart transplants. Further, we question the basic premise that there is, in fact, such a thing as an "uncomplicated" transplant patient. Absence of a condition on the MCC list does not, in our view, equate with a low complexity or low cost. In fact, based on our review of the MCC list, we believe there are many patients with complicated and, consequently, high cost hospital stays whose admissions would not fall into the higher "w/MCC" DRG. However, more importantly, the factors that have consistently been identified in the literature with a positive correlation with complexity and cost – donor risk, and MELD status for liver transplant patients- were not included in the development of the MS-DRGs for transplants.

1. Donor Risk Index

One factor that influences hospital costs and lengths of stay is the characteristics of the donor organ. Liver transplantations involving expanded criteria donors (ECDs) and donors after cardiac death (DCD) have been associated with longer lengths of stay (LOS) and increased costs, regardless of the condition of the recipient. [2] In one study, in comparable recipients, the use of organs with high donor risk index (DRI) was associated with an increase in LOS of 10.6 days with incremental costs of $47,986. *Id.* (Although this study involved both Medicare and non-Medicare patients, we have no reason to believe the data for Medicare patients alone would be any different.) Given the increasing demand for transplantable organs, the push from the Health Resources and Services Administration to utilize more of these higher risk organs, heart and liver allocation systems that rightly prioritize sicker (more costly) patients and the large number of individuals on waiting lists around the country, use of DCD and ECD donors is increasing. Therefore, it is important that any severity index for transplant DRGs take these factors into consideration. Currently, the MS-DRG methodology is not able to take donor risk into account because DRI is not captured in the MedPAR data base. ASTS would like to work with CMS to

[2] Axelrod D, et. al., *The Economic Impact of the Utilization of Liver Allograft with High Donor Risk Index*, Am. J. of Trans. 2007; 7:990-997 (Attachment 1).

refine the IPPS system so that factors such as the DRI can be included in determining DRG assignment either through the development of diagnostic ICD-9 "V" codes or some other mechanism. ASTS is in the process of developing a strategy to achieve this objective. However, until such new ICD-9 codes or other refinements can be implemented, we do not believe it is appropriate to have severity-based DRGs for heart and liver transplant procedures based on CC or MCC that have not been validated as predictors in the transplant populations

2. MELD Status for Liver Transplants

The model for end-stage liver disease (MELD) system, adopted in February of 2002, prioritizes patients awaiting liver transplants by severity of illness. Use of the MELD system has led to a reduction in overall mortality, especially among the sickest patients – those with the highest MELD score. Patients with high MELD scores have longer hospital stays and incur substantially higher hospital costs. Moreover, many patients with high MELD scores have renal failure and thus required a combined liver/kidney transplant. In one study, increasing MELD score was associated with higher costs of $4309 per MELD point. [3] Any severity-based DRG system for liver transplant should take into consideration the patient's MELD score. Currently, however, this information is not captured in the MedPAR data base; consequently, the proposed MS-DRGs for liver transplants do not take this into consideration.

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In summary, there appears to be little benefit associated with the MS-DRGs for heart and liver transplants. It is unlikely to increase accuracy of payment since the major risk factors associated with these procedures have not been taken into account. Moreover, the significant fluctuations in DRG payments from one year to the next will have a destabilizing impact on transplant centers.

III. Separate DRG for Liver/Kidney Transplants

Once again, we would like to request that CMS consider creation of a separate DRG for combined liver/kidney transplants. Currently, liver and liver/kidney transplants are assigned to a single MS- DRG for liver transplants. While we believe that the renal failure accompanying most liver-kidney transplants would result in assignment to the "with MCC" liver transplant DRG, we continue to believe that a separate DRG is needed to address the significantly higher costs associated with combined liver/kidney transplants. We raised this issue in FY 2008, FY 2007 and FY 2006 in our comments on the proposed IPPS rule. CMS has previously acknowledged that the costs for a liver-kidney transplant were significantly higher and lengths of stay were considerably longer than those associated with liver transplants alone. Specifically, FY 2004 MedPAR data showed average charges for liver/kidney transplants of $237,759 and average LOS of 21.3 days compared with $165,314 for liver transplantation. (See August 12, 2005 Federal Register at 47286) However, CMS determined that there were too small a number of cases (79 out of 959) to justify creation of a new DRG at that time.

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[3] Axelrod D., et al., *The Economic Impact of MELD on Liver Transplant Centers,* Am. J. Trans. 2005; 5: 2297-2301 (Attachment 2). Although this study involves both Medicare and non-Medicare patients, there is no reason to expect that Medicare-only data would differ.

With respect to the relatively small number of cases, we note that with the February 2002 implementation of the model end stage liver disease (MELD) system to prioritize patients, there has been a substantial increase in the number of patients receiving liver/kidney transplants. [4] This is due, in large part, to the fact that high creatinine levels affect the MELD score more than other variables. Thus, many of the patients who are priority candidates for liver transplants also have impaired kidney function. In a study at one large transplant center, liver/kidney transplants were 6% (n=5) of the total number of liver transplants prior to implementation of the MELD system but 17% (n=22) post-MELD.[5] That same study found that hospital costs for inpatient stays involving combined liver/kidney transplants were 124% higher than liver transplants alone and the average LOS was 144% longer.

Further, outlier payments are generally inadequate. In the study referred to above, 19% of liver/kidney cases fell in the outlier gap and 44% achieved outlier status. However, the transplant center calculated that its average per case loss for outlier cases was over $17,000 per liver/kidney transplant. Those that did not qualify for outlier payments resulted in a loss of over $19,000.

We believe hospital inpatient costs and LOS associated with a liver/kidney transplant are sufficiently higher than those of a liver transplant alone as to justify the creation of a separate DRG. We ask that CMS re-evaluate, in light of the most recent available data, its earlier decision that there was insufficient volume to justify a separate DRG. We believe the recent increases in volume justify creation of a separate DRG for combined liver/kidney transplants.

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We thank you for considering these comments. If you have any questions, please contact the ASTS Executive Director, Katrina Crist, at 703.414.7870 or katrinacrist@earthlink.net.

Sincerely,

JPR

John P. Roberts, MD
President

[4] OPTN data shows 246 cases (Medicare and non-Medicare) in 2003, 279 in 2004, 337 in 2005, and 399 in 2006 and 440 in 2007.

[5] Axelrod DA, et al., supra, note 3.