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Re: Process for Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers

Dear Mr. Hamilton:

ASTS is very pleased to respond to your letter of July 17, 2008 asking for our comments on the CMS draft document entitled "Process for Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers" ("the Draft"). We have reviewed the Draft and believe it lays out a very thoughtful and reasonable structure for the implementation of the mitigating factors provisions in the regulations. Our comments and recommendations are set forth below.

1. Compliance with Outcomes Measures

Appendix A to the Draft identifies mitigating factors related to a transplant center's failure to meet the outcome measures. The standard related to outcomes is probably the most complex of the CoPs and the one most likely to be the subject of requests for consideration of mitigating factors. CMS has stated that it will cite a condition-level deficiency if more than one of the most recent five (5) SRTR reports do not meet outcome requirements. We are concerned that a rigid application of this condition could result in centers refusing to accept high-risk patients.

We have also long been concerned that this policy, if applied strictly, could result termination of centers that generally provide high quality care; in fact, we do not believe that two failed SRTR reports should ever be the basis for a termination action unless other aggravating circumstances are present. Further, as we have noted previously, despite the 210 day correction period, a failed SRTR report cannot generally be cured since it is based on events that have already happened.

As you may know, the OPTN committees are currently providing input to the SRTR on revisions to the variables used for risk-adjustment that result in Program-Specific Reports (PSRs) for transplant programs. These changes will result in different "expected" outcomes which form the "anchor" used in calculating whether a program's results are statistically significantly worse than expected. In fact, several new variables have recently been added to the SRTR models as risk predictors that were not included in previous analyses. One example of this is donor age for HCV positive recipients. We believe that SRTR does not plan to apply these variables retrospectively to existing PSRs. Perhaps more relevant to our concern is the fact that 1) there are variables that may be important to risk-adjustment, particularly on the recipient side that are not being collected as part of the data submission requirement, and 2) data included in current OPTN forms have not been collected uniformly over the past few years, yielding analyses that may not accurately reflect their impact in current risk adjustment methodologies. Examples of this include specific characteristics of hepatocellular carcinoma (HCC) known to have predictive strength and the severity of co-morbidities, including coronary artery disease (see below). Therefore, it is clear that variables used in risk-adjustment are evolving and that the necessary data may not be available to capture all significant risk predictors. These ongoing changes underscore the thesis that current risk-adjustment methodologies may not allow for their use as sole determinants of quality of care.

Thus, it is essential that transplant centers identified as having poor outcomes be given an opportunity to explain and sufficient time to improve. This will render the mitigating factor review critical in ensuring that good centers are not inappropriately denied or revoked.

We would like to reaffirm, however, our complete and unwavering support of CMS' efforts to identify underperforming centers. Certainly, centers with poor outcomes that lack any legitimate justification and which do not undertake effective remediation should not be permitted to participate in the Medicare program. ASTS is committed to assisting CMS in the identification of such centers.

- **Risk-Adjustment Anomalies**

We would like to comment on the provision related to risk-adjustment anomalies. We are supportive of CMS' indication that it will consider transplant risks that may not be captured in the SRTR risk-adjustment methodology as well as the role that experimental protocols may play in a center's outcomes. We believe review of these factors should be

as flexible as possible and therefore appreciate that the Draft does not attempt to list or otherwise limit the factors that can be considered.

However, we thought it would be useful to identify and provide background on some of the risk-adjustment factors that we believe are relevant. This discussion is by no means exhaustive and there are a great many other factors that might be appropriately considered. Moreover, we are not suggesting that presence of these circumstances is a mitigating factor that represents a per se justification for approval of a center but rather that such factors should be entitled to consideration.

i. ABO or Crossmatch Incompatibility – Desensitization Procedures

The medical literature demonstrates that kidney transplant patients who undergo desensitization procedures due to ABO or crossmatch incompatibility generally have poorer outcomes than patients who do not require desensitization. Further, although ABO incompatibility is identified as an SRTR risk factor, crossmatch incompatibility is not. Desensitization is typically performed when a patient is offered a kidney from a living donor, such as family member, and there is either ABO or crossmatch incompatibility between the donor and recipient. In order to avoid rejection of the donated organ, it is necessary to desensitize the patient prior to the transplant and to maintain the desensitization protocol even after the transplant, often for a period of months or years. Kidney transplant recipients who undergo desensitization to address incompatibility issues have been demonstrated to have poorer outcomes, but have better outcomes than remaining on dialysis.

ii. Hepatocellular Carcinoma (HCC)

One of the primary indications for a liver transplant is HCC. A diagnosis of HCC and the stage of the disease (as defined by specific prognostic factors) are risk factors for liver transplants. Although malignant diagnosis is risk-adjusted by the SRTR, factors which can impact whether the patient will have a recurrence of their cancer which can impact patient survival include, among others, the TNM stage, the degree of differentiation, the level of alpha-fetoprotein, and the presence of microvascular invasion are not available for all patients with HCC receiving transplants and cannot be included as variables in risk-adjustment. Therefore, a transplant center that has an aggressive program for transplanting patients with HCC could see outcomes that are inferior to those of centers that do not aggressively transplant patients with HCC. Depending on the circumstances and medical appropriateness, this may be an acceptable mitigating factor.

iii. Cholangiocarcinoma

Cholangiocarcinoma, or cancer of the bile ducts, is another risk factor that is not explicitly considered in the SRTR risk-adjustment methodology (although a malignant diagnosis is considered). This cancer has a 30% to 90% recurrence rate after transplantation. Yet transplantation is often the only potentially curative option for such patients. Transplant centers that have a program that aggressively transplants patients

with this diagnosis may have outcomes that are much better than projected above, but that do not meet the SRTR measures. Again, this may be an acceptable mitigating factor.

iv. Hepatitis C Virus

The presence of hepatitis C virus (HCV) is another factor that can negatively impact outcomes and that should be considered as a component of the analysis of mitigating factors. As stated above, only recently has donor age been included in risk-adjustment for HCV liver recipients (to be included in future SRTR analyses). Also, HCV positive kidney recipients may not meet SRTR measures especially if HCV positive kidneys are used. This raises two issues: first, the fact that donor age for HCV patients will not be considered in previous PSRs and second, this may be an acceptable mitigating factor for kidney recipients.

v. Coronary Artery Disease and Other Co-Morbidities

The presence and severity of coronary artery disease, coronary vascular disease, peripheral vascular disease, as well as a number of other co-morbidities that can impact patient survival are not fully reflected in the SRTR reports because of limitations in currently reporting of these factors to the OPTN. We feel these should be considered as possible mitigating factors. The medical literature has identified a number of specific co-morbidities that result in worse graft and survival rates, not all of which are included in the SRTR methodology. For example, a recent 5-year analysis at 241 kidney centers that looked 1-year graft survival with and without adjustment for comorbidities, concluded that failure to adjust for pre-existing recipient comorbidity results in grossly inaccurate estimation of expected graft failure. Therefore, using data that are not adjusted for co-morbidity to judge the quality of transplant centers may not lead to an accurate assessment of quality of care. Moreover, this could encourage centers to "cherry pick recipients" resulting in denial of access to patients with significant comorbidities.

[Weinhandle E, Snyder J, Israni A, Kasiske B. *Centers for Medicare and Medicaid Services Outcome Requires for Transplant Centers and the Importance of Proper Adjustment for Comorbidities.* Presented ATC 2008].

2. Information to Be Presented to CMS

The Draft identifies several types of information that should be submitted in connection with a request for review of mitigating factors. We suggest that, at least where the outcomes standard is at issue, that the center should be allowed to provide any additional data viewed by the center to be relevant as explanations for inferior outcomes. In other words, the center should be allowed to "make their case" without imposing any restrictions as to what the center submits. This could include the centers' own risk-adjustment as long as the appropriate rationale (evidence-based) is submitted.

3. Role of National Panel

A consideration of mitigating factors, particularly as applied to outcomes standards, raises a number of complex clinical and statistical issues. Therefore, we are pleased that review of mitigating factors will be handled by the CMS national office and that a national panel comprised of CMS staff with clinical expertise will review all such requests. However, we would urge that CMS include in the Panel, as appropriate, individuals at other HHS agencies such as the Division of Transplantation in HRSA who may have special expertise in the field of organ transplantation.

4. Advisory Group of Transplantation Professionals

In addition, we believe the transplantation professional community could have a vital role to play in this process by providing expert consultation and guidance to the CMS national panel on a case by case basis. We recommend that CMS establish a process for the convening of an advisory group of outside experts who could, with the transplant center's agreement, provide guidance to CMS in evaluating a transplant center's evidence of mitigating factors. Such an advisory group would be convened at the discretion of CMS depending on whether the agency believes that guidance from outside experts would assist it in properly evaluating center's proffered mitigating factors. For example, if a center asserted mitigating circumstances with respect to the outcomes standard based on a disproportionate number of high-risk patients with respect to factors not adjusted for in the SRTR models, the advisory panel could provide assistance in 1) confirming that the risk factors were not included in the SRTR methodology, whether they were clinically appropriate, 2) assessing whether and what extent the outcomes standards would have been met if the high-risk patients were excluded from the SRTR calculation, and 3) determining whether the corrective action plan offered by the center is acceptable.

We suggest that such an advisory group include at least one ASTS-member transplant surgeon with expertise in the specific organ program at issue. In addition, a transplant physician, an administrator and, where appropriate, statistical support should be included. The transplant center would pay the costs associated with the advisory group. The members of the advisory group would be selected by CMS.

The ASTS further offers its assistance to CMS in managing and providing access to a pool of highly qualified transplant surgeons to participate in reviews on behalf of CMS. We would be pleased to discuss this in more detail if there is interest on the part of CMS.

We would also recommend that for mitigating circumstances based on outcomes, even if a center is able to successfully demonstrate mitigating factors, the center should be evaluated after one year and its interim SRTR reports analyzed. The advisory group could provide guidance to CMS as to whether those reports indicate appropriate progress.

The advisory group would have no independent decision making authority and would make its recommendations to CMS.

In addition to providing advice during the mitigating factor review process, the advisory group could also provide guidance to CMS contractors during the denial and corrective action process by helping to evaluate whether a program that is denied based on outcomes has presented an adequate plan of correction and whether, at the end of the 210 day compliance period, it has achieved compliance.

5. Procedural Issues

- **Date of Notification Letter:** The Draft indicates that a transplant center seeking review based on mitigating factors has 10 days from the date on the notification letter to submit certain information and 30 days from that date to submit more extensive information. We would suggest that the 10 and 30 day periods run from transplant center receipt of the letter, which can be deemed to be 5 days from the date on the letter, absent evidence to the contrary. This is consistent with other Medicare appeal deadlines in which the deadline is based on the date of receipt of the notification which is deemed to be 5 days from the date on the notice. See, e.g., 42 CFR §405.1002; 405.962.

- **Notice to Center of Opportunity for Review Based on Mitigating Factors:** We would also suggest that the notification letter to the center clearly state the opportunity to present mitigating factors, how to do so, and the relevant deadlines.

- **Relationship between Review based on Mitigating Factors and Corrective Action Process:** We are concerned that there may be confusion as to how the review of mitigating factors and the deadlines applicable to that process interact with the process and deadlines applicable to the corrective action process and its deadlines. For example, a center would not know whether it had been approved based on mitigating factors before it has to submit a plan of correction in connection with a negative decision on certification. Moreover, the information that is due within 30 days under the mitigating factors review (i.e. items 5 – 8) would appear to be relevant to development of a corrective action plan if the mitigating factors are not accepted. However, if the corrective action plan must be submitted within 10 days, this would not allow that process to inform the development of the corrective action plan. We are also concerned that there will be two corollary reviews by two different parts of the agency taking place simultaneously and that the two parts will not necessarily know what the other is doing. This could result in inconsistent decisions or advice. It would seem to make more sense to first determine whether a transplant center can be approved based on review of mitigating factors and then start any corrective action process that may apply. If it is determined that the mitigating factors will not be accepted, the deadline for submission of a corrective action plan could run from the date of that

decision. At the very least, however, we believe it is important that the national panel reviewing mitigating factors and the state survey agency reviewing the corrective action plan we in communication with each other to ensure a smooth and effective process.

- **Deadline for Submission of Data on Internal Program Improvements:** The Draft states that programs would have 30 days to submit evidence of internal program improvements such as an analysis of the basis for non-compliance with a CoP and reporting changes that have been made as a result of the analysis. We believe 30 days is a very short period of time to undertake these types of program improvements and suggest a longer period might be appropriate.

- **Deadline for Submission of Corrective Action Plan:** The Draft states that transplant programs that seek review based on mitigating factors must still develop and implement a plan of correction within 10 days of the notification letter. As stated above, we believe the corrective action plan should not be required until after a decision has been reached on the mitigating factors. Further, 10 days to develop a correction plan is an extremely short period of time regardless of whether mitigating factors are an issue or not. This would not appear to give a center's management sufficient time to review and investigate deficiencies, obtain input from relevant departments and individuals, and establish an effective corrective action plan with appropriate goals and timetables. We would suggest that, absent an imminent threat to patient safety, that centers have at least 30 days to submit such a plan or that they have 10 days to submit a preliminary plan with additional time, such as is allowing for review of mitigating factors, to refine the plan.

We appreciate the opportunity to provide input on this process. If you have any questions, please contact the ASTS Executive Director, Katrina Crist, at 703-414-7870 or katrina.crist@asts.org.

Sincerely,

John P. Roberts, MD
President

Cc: Karen Tritz