ASTS
American Society of Transplant Surgeons

May 12, 2008

Thomas E. Hamilton
Director
Survey and Certification Group
Centers for Medicare and Medicaid Services
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Dear Mr. Hamilton:

As President of the American Society of Transplant Surgeons, I am writing to you to follow up on our last meeting. As promised, please find enclosed our suggested revisions to the most recent Interpretive Guidelines (IGs). We hope that these comments are helpful to CMS in finalizing the IGs.

In addition, three other matters have come to our attention that we believe warrant further discussion. These are outlined briefly below:

First, we are enclosing our suggested revisions to, and comments on, the Survey "Protocol," which came to our attention after our last meeting. In this regard, please note that both the Protocol and the IGs repeatedly direct surveyors to review medical records and other documents pre-dating June 28, 2007, when the new transplant center regulations became effective. **We believe that this is entirely inappropriate, and request that, at a minimum, CMS issue instructions to surveyors cautioning them to survey transplant centers for compliance with the new requirements only for periods on and after June 28, 2007.** This would apply new law retrospectively, which seems to be in violation of the legal process.

Second, since our meeting, we have had the opportunity to review the potential implications of the "Guidance for Citing Condition and Standard-level Deficiencies for Certain Regulatory Requirements and Allowing Additional Time to Correct the Deficiency" ("Guidance") dated April 4, 2008. We have several serious concerns about the Guidance.

Specifically:

- The Guidance criteria for distinguishing "standard-level" from "condition-level" deficiencies are much too rigid and stringent. In this regard, it is our understanding that, when a transplant program's most recent SRTR report fails to meet outcomes requirements, surveyors are directed to review patient and graft survival rate over the most recent two-year period. A condition level deficiency will be found (and a publicly available notice of termination will be sent to the center) unless the center (a) has both patient and graft unadjusted survival that is at 100% during this period; or (b) has only one SRTR center-specific report out of compliance during this two year period. Regarding the first, 100% is only a theoretical outcome with little or no support in reality. The second is likewise extremely unrealistic. As a result, very few of the foremost high quality centers, if any, may be found in compliance at the "condition level," potentially resulting in the issuance of numerous unwarranted Medicare termination notices, albeit with the opportunity for affected centers to take corrective action within 210 days.

- The Guidance does not provide any opportunity for a transplant center to share data with the surveyors or with CMS on "mitigating circumstances" that would justify the center's failure to meet the outcomes standard, or that might result in a finding of a "standard-level" rather than a "condition-level" deficiency.

- It is unclear to us how a center that is found to be out of compliance with the outcomes standard at the "condition-level" can take effective action to avert termination, since the center will be unable to affect the SRTR outcomes data within the 210 days provided for corrective action.

Third, a significant technical issue has come to our attention: Even though the IGs, the Guidance, and the Protocol all appear to assume that the CMS outcomes standard is the same as that used in the SRTR center-specific reports, one of the three statistical measures used by CMS to determine compliance with the outcomes standard deviates from that used by the SRTR in reporting center-specific outcomes. The Medicare regulations use a "one-tailed" p value to measure the extent to which observed survival is lower than expected survival; however, the SRTR center-specific reports use the "two tailed" p value. Using the "one-tailed" p value results in a more stringent Medicare outcomes requirement than that used in the SRTR "center-specific reports." We are unclear about whether this result was intended, but we believe that it is inappropriate. We previously discussed and agreed to the importance for CMS and SRTR to use the same methodologies in order to prevent confusion and an untenable situation for the transplant community.

We would appreciate the opportunity to discuss these matters with you further, and will be in touch shortly to determine a mutually convenient time. Thank you again for your willingness, and the willingness of your staff, to engage in an open dialogue with us

regarding the implementation of the transplant center CoPs. We look forward to continuing to work with you on these important issues.

Sincerely yours,

Goran B. Klintmalm, MD, PhD, FACS
President