POWERS
PYLES
SUTTER &
VERVILLE PC
ATTORNEYS AT LAW

Twelfth Floor
1501 M Street, NW, 7th Floor
Washington, DC 20005
Phone: (202) 466-6550 Fax: (202) 785-1756

# MEMORANDUM

To: ASTS; Attn: Katrina Crist

From: Rebecca Burke and Diane Millman

CC: Michael Abecassis, MD; Goran Klintmalm, MD; John Roberts, MD

Date: June 18, 2008

Re: Additional Modifications of IGs made in response to ASTS concerns

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We have reviewed the final Interpretive Guidelines that were transmitted to us by CMS earlier this week. We continue to be impressed that CMS has made significant changes in response to the major concerns raise d by ASTS. Below is a summary of the major modifications made in response to ASTS concerns. Also attached is a marked up copy of the final IGs which highlights the changed sections with our comments and annotations.

- **Effective date:** CMS has amended the IGs throughout to indicate that transplant centers (TCs) will only be reviewed for compliance after the June 28, 2007 effective date of the regulations.
- **Multidisciplinary teams:** The final IGs provide for more flexibility with respect to documentation that care was furnished by a multidisciplinary team. Tag 82 adopts ASTS language, which eliminates reference to post-discharge care in some places and generally provides for more flexibility including a statement that it is not necessary for all members of the team to be involved in all aspects of care. In addition, ASTS language that documentation of multidisciplinary team care can be in the form of notes in the record was adopted. In the cover letter accompanying the revised IGs, CMS specifically addresses the issue of multidisciplinary care and notes that formal team meetings are not required and that there are other ways to document multidisciplinary care, such as a form in

the medical record, written documentation of verbal communication among different disciplines, or progress notes.

- **Living Donor Assessment:** The regulation requires that the TC document the living donor's suitability for donation. Tag 59. The draft IG would have required an actual meeting of the multidisciplinary team to discuss the donor's suitability. The final version would not require a team meeting if there is evidence in the medical record or elsewhere of a "formal process" by which all team members can raise issues and concerns regarding donor suitability.
- **TPQR Report:** CMS accepted ASTS language, which states that surveyors may provide a copy of the TPQR to TCs during the onsite survey.
- **Scope of Survey:** The final IGs clarify that the survey for compliance with CoPs does not include the outpatient clinic (except to interview transplant patients about their inpatient experiences).
- **Post-Discharge Obligations of the TC:** The final IGs recognize that the discharge plan can call for patients to be followed by the local physician and eliminate the reference to a required six-month follow-up period.
- **Requirements for Transplant Surgeons and Physicians:** Tag 125 adds a requirement that transplant surgeons be licensed under state law, meet hospital credentialing and privileging requirements, and have "current Board certification, or approval from OPTN of foreign equivalency.
- **Tissue-Typing:** The final IGs clarify that tissue typing services are not required to be provided on a 24-hour basis.
- **Pediatric v. Adult Certification:** CMS responded to ASTS concerns that the IGs in this area were confusing and inconsistent and has added clarifying language, though this remains a confusing area. (Tag 21)
- **Clinical Experience Requirements:** CMS added ASTS language clarifying that for re-approval, the 10 transplants per year could be satisfied by an average of 10 over a period of three years.

Thus it appears that the activities of ASTS have resulted in substantial improvements in the IGs and in the process to be used in conducting the surveys overall. It is particularly significant that CMS has limited the authority of on-site reviewers to require the production of medical records and other documents that pre-date the effective date of the regulations. ASTS involvement also has resulted in changes related to documentation of the multi-disciplinary team, which has been an area that has generated a significant number of deficiency findings for transplant centers.

At this stage, we suggest that ASTS turn its attention to other aspects of the Medicare certification program for transplant centers, including, for example, the criteria for distinguishing condition from standard level deficiencies in the outcomes requirements, clarification of the types of corrective action that will be deemed to be sufficient for deficiencies related to data submission, outcomes, and clinical experience requirements, and the definition and application of "mitigating circumstances" for deviations from expected outcomes. We look forward to working with you on these issues.