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May 31, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

RE: CMS-3835-P

Dear Dr. McClellan:

The American Kidney Fund is our nation's leading voluntary health organization serving people with and at risk for kidney disease through direct financial assistance, comprehensive education, clinical research and community service programs. The Fund is pleased to provide our comments on the proposed revisions to the Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants [hereafter, Conditions of Participation](CMS-3835-P).

The Fund appreciates CMS' undertaking this ambitious effort to update the Conditions of Participation. We also support the emphasis on quality patient care based on outcome-oriented and process-oriented requirements, rather than solely on numbers of transplants.

The Fund's specific comments on the Conditions of Participation are listed below, by section.

## **PATIENT AND LIVING DONOR SELECTION**

### **C.1. Section 482.90**

The Fund believes transplant centers should be required to make their patient selection criteria available to patients routinely, rather than only by request. These criteria should be published in the Annual Reports of the Organ Procurement Transplant Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR).

Likewise, we suggest living donor selection criteria should be made available routinely and published in the Annual Reports of the OPTN and SRTR.

In addition, the Fund recommends adding a requirement that a kidney transplant center's selection criteria for both transplant recipients and living donors must be shared on a routine basis with the nephrologists and dialysis centers which refer patients to that transplant center.

## **ORGAN RECOVERY AND RECEIPT**

### **C.2. Section 482.92**

The Fund requests clarification of the proposed requirement that “a transplant center’s organ recovery team would have to review and compare the intended recipient and donor data *before* recovery takes place.” While we favor safeguards to ensure compatibility between intended recipient and donor, we are concerned about the possible delay in recovering donor organs while testing is completed. This could result in a lost opportunity to recover the organs as well as share recovered organs locally, regionally or nationally if not compatible with the initially intended recipient. The Fund supports protocols designed to prevent blood type incompatibility and positive cross-match renal transplantation, but without interfering with the recovery process. Cross-match validation should certainly take place prior to renal transplantation.

## **PATIENT AND LIVING DONOR MANAGEMENT**

### **C.3. Section 482.94**

The Fund applauds CMS’ inclusion of requirements defining the transplant center’s responsibility to living donors. We favor extending this requirement to include medical, graft, and patient survival data reporting one year post-transplant which is consistent with recipient follow-up requirements.

We also suggest that CMS explore ways to require, and provide Medicare reimbursement for, follow-up medical care to living donors for up to three years post-donation. Medical care for living donors has the potential to increase the number of people willing to donate organs. This could result in considerable savings to Medicare since the care of kidney transplant recipients costs far less than that of dialysis patients. Transplants from living kidney donors have become such an important source, exceeding deceased donor kidney transplants, the post-donation follow-up care will not only routinely address potential problems, but also provide important longer term living donor follow-up data for individual centers, regions, and the national transplant program.

The Fund supports the requirement that transplant centers maintain up-to-date and accurate patient management records for waiting list patients. In addition, we urge that coordination of this information with referring nephrologists and dialysis centers be required. In order to accomplish this in kidney transplantation, interoperable electronic records systems should be established among referring nephrologists, dialysis centers, and transplant centers.

The Fund agrees that it is important for transplant centers to inform patients of their transplant waitlist status initially and annually thereafter. We also concur with the requirement for multi-disciplinary care

planning. Further, we suggest the clinic waiting time for transplant candidates, recipients and living donors be utilized to provide education and group support sessions and, as in the dialysis conditions of coverage, centers document that patients have demonstrated their understanding of the information provided.

We strongly support the requirement for transplant candidates, recipients and living donors to have ongoing access to qualified social workers. We agree with the definition of qualified social worker as an individual who meets licensing requirements in the State where practicing and has completed a graduate degree from an accredited school of social work. In order to retain the services of skilled renal transplant social workers who do not meet these requirements, we also support the grandfathering of those with at least 2 years experience, one of which was in a transplantation program and who have established a consultative relationship with a social worker who meets the definition. A United Network for Organ Sharing study showed social workers who report to the transplant department, rather than other hospital departments, are better able to intervene. Therefore, we recommend social workers be dedicated to the transplant program whenever financially feasible.

## **HUMAN RESOURCES**

### **C.5. Section 482.98**

The Fund commends CMS for including ACOT's recommendation for each transplant center to provide an independent advocate or advocacy team for potential living donors. We believe this is important in order to ensure that the donor's interests are protected and to help donors understand the process, procedures and risks and benefits and we favor requiring this provision. We also suggest that social workers with Masters of Social Work degrees may be an appropriate professional resource for this position, but independent from the social worker employed by the transplant center to work with potential recipients.

The Fund recommends CMS review and possibly revise safeguards protecting patient records and confidentiality (waiting list patients, prospective and past donors and recipients). Given the increased risks of losing sensitive data to hackers, identify theft, and stolen laptops; we trust the interpretation of the HIPAA regulations (or the regulations themselves) will evolve with changes in technology.

The American Kidney Fund appreciates this opportunity to comment on the proposed regulations. Since the Fund's mission is dedicated to improving patient access and quality of care and outcomes, we'd be pleased to meet with you to discuss our comments prior to the promulgation of the final regulations.

Sincerely,



Andrew T. Givens  
Chair, Board of Trustees