



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Healthcare Systems Bureau

Health Resources and  
Services Administration  
Bethesda MD 20814

October 29, 2004

Walter K. Graham, J.D.  
Executive Director  
United Network for Organ Sharing  
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Richmond, Virginia 23219

Dear Walter:

Thank you for your letter of October 28<sup>th</sup>. In response to a previous request from the Organ Procurement and Transplantation Network (OPTN), the Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB), Division of Transplantation (DoT) has been considering the scope of the OPTN's authority over living donation matters under the current OPTN contract and the OPTN Final Rule.

Over the past 4 years, national rates of living donation have seen substantial increases. Because of the rich experience of many OPTN-member institutions, the OPTN can play a leading role in assuring the safety and efficacy of organ transplants made possible by living donors.

Until recently, OPTN policies have predominantly focused on issues related to organ donation and transplantation of deceased donor organs. However, several widely publicized living donor deaths have caused the OPTN to implement new policies to review and approve qualifications of living donor transplant programs. Additionally, the increased incidence of altruistic living donations requires the OPTN to consider organ allocation policies that are patient-focused yet address the unique circumstances pertaining to the recovery and transplantation of living donor organs.

At its June 2004 meeting, the OPTN Board of Directors passed the following resolution: "RESOLVED, that the Board of Directors actively work toward developing a national system that facilitates living non-directed donation within the mandates of the OPTN and meets the needs of the transplant community." This resolution, and other living donation-related activities conducted by the OPTN has raised questions about the OPTN's involvement especially in light of language found in §121.4 (a)(1) of the OPTN Final Rule (42 CFR Part 121) which states the OPTN Board is responsible for developing policies within the mission of the OPTN as set forth in NOTA, including "[p]olicies for the equitable allocation of cadaveric organs."

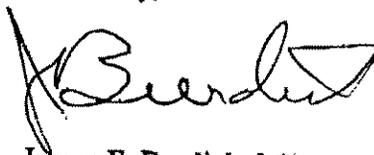
Page 2 – Walter K. Graham, J.D.

However, the Final Rule also provides that the OPTN shall be responsible for developing policies on a variety of topics, including “[p]olicies on such other matters as the Secretary directs.” In accordance with that authority, HRSA, HSB, DoT is directing the OPTN to develop allocation guidelines for organs from living donors. These guidelines should be limited to the allocation of organs from living donors made to an anonymous pool, and not to organs procured in connection with directed donations. The DoT also is directing the OPTN to develop other voluntary policies/guidelines (not pertaining to organ allocation) it believes necessary and appropriate to promote the safety and efficacy of living donor transplantation for the donor and the recipient. This includes guidelines pertaining to public solicitation of donated organs from living donors as well as deceased donors, consistent with §121.8(h) of the Final Rule concerning directed donations. We would be happy to assist the OPTN in determining whether particular donations constitute directed donations. As with all existing OPTN policies, those related to living donor transplantation must be subject to the same public comment processes as other OPTN policies.

All OPTN policies on living donation (other than data reporting policies) should be considered as best practices or voluntary guidelines and not subject to regular OPTN sanctions. In the event a member fails to abide by best practices/voluntary guidelines developed by the OPTN, appropriate responses the OPTN could take may include a public statement of such non-compliance or referral to the Department of Health and Human Services in the event that the practice poses a threat to public health or safety. If you wish living donor guidelines to have the same status as other OPTN policies we would want to issue a Federal Register notice inviting public comment on that matter.

Thank you for your attention to this issue. If you have questions, or if I can provide additional information, do not hesitate to contact me.

Sincerely,



James F. Burdick, M.D.  
Director

cc: Richard Durbin, Deputy Director, DoT  
Lorah Tidwell, Chief, Operations and Analysis Branch, DoT  
Virginia McBride, Project Officer  
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