



JUN 15 REC'D

Rockville, Maryland 20857

JUN 10 2005

Mr. Walter K. Graham
Executive Director
United Network for Organ Sharing
700 North 4th Street
Richmond, Virginia 23219

Dear Mr. Graham:

The purpose of this letter is to inform the United Network for Organ Sharing (UNOS) that data submitted to the Organ Procurement and Transplantation Network (OPTN) by organ procurement organizations (OPOs) and transplant hospitals are considered mandatory under § 121.11(b)(2) of the OPTN final rule. Failure of an OPO or transplant hospital to submit the data accurately and completely could be considered in violation of this section.

The final rule governing the operations of the OPTN became effective March 16, 2000. Section 121.11(b)(2) provides that:

“[a]n organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.”

Additional notice of the enforceability of this provision under section 1138 of the Social Security Act can be found in the preamble of the April 2, 1998, final rule discussing the definition of “rule or requirements of the OPTN” for purposes of implementation of section 1138 (63 Fed. Reg. 16296 (1998)). On page 167301, the Department states that it considers a “rule or requirement of the OPTN” to be those rules developed as provided for in the regulations. The Department uses the data submission requirement found in §21.11(b)(2) as an example:

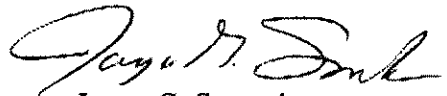
“an OPO or transplant hospital participating in Medicare or Medicaid could be considered in violation of section 1138 if the Secretary found that it did not provide information to the OPTN as required specifically by § 121.11(b)(2)”

Data "specified by the Secretary" include the data found on the OPTN forms and applications reviewed and approved by the Office of Management and Budget (OMB) (OMB packages No. 0915-0157, expiration on August 31, 2007, and No. 0915-0184, expiration on December 31, 2007). Violations of the accuracy and completeness of the data submission requirements provided in the final rule could subject an OPO or transplant hospital to appropriate sanctions including, but not limited to, those relating to participation in or reimbursement under Medicare and Medicaid programs and removal of designation as a transplant program.

Given the potential consequences of violating this requirement, UNOS should provide OPOs and transplant hospitals with adequate notice of this mandatory data submission requirement and the potential consequence of violations under section 1138. This notice can be achieved through a message on the UNet system at the time of user entry into the system and any other appropriate methods.

If you have any questions, please contact Jim Burdick, M.D., Director, Division of Organ Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, at (301) 443-7577.

Sincerely,



Joyce G. Somsak
Acting Associate Administrator