



American Society of Transplant Surgeons

August 31, 2012

John P. Roberts, MD
President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear Dr. Roberts,

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment on the OPTN Policies Plain Language Rewrite proposal out for public comment through August 31, 2012. While ASTS appreciates the OPTN's efforts to translate the complex wording and organization of OPTN policies into plain language, the draft document fails to achieve this objective and appears to make unwarranted changes to the current policies that we cannot support. We respectfully **oppose** adoption of the draft document in its current form.

Based on OPTN public statements regarding the Policies Plain Language Rewrite, the primary aim was to make the documents more readable and easier for transplant professionals, patients and the public to understand and use and should not alter the substance or meaning of the existing material (emphasis added). While this is laudable in theory, it is difficult to utilize plain language in describing complex medical policies that carry penalties if not strictly adhered to. Given the consequences of an adverse OPTN finding, the emphasis should be on clarity as opposed to plain language. Priority should be placed on precise definitions, clear terminology, and logical sequencing that do not change the meaning and requirements of the current policies. If adopted in their present form, the policies have the potential to obfuscate the procedures to be used by transplant centers, organ procurement organizations and others in the organ donation and transplantation process.

Our review of the draft document has generated significant concerns based on the inclusion of seemingly new or revised requirements while, at the same time, excluding relevant information from the current policies. There are also areas where the changes create too much of a prescriptive tone compared to the current policies.

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For example, in proposed policy 19.1, *Requests for Data*, there is additional language, when compared to current policy 9, *Releases of Information to the Public*. It states “If a requestor does not comply with any requirements of Policy 19: *Release of Data*, then the OPTN Contractor may withhold additional data from future data requests.” While we may agree that this is appropriate, it appears to be an addition to the policy and not simply a plain language rewrite as intended.

Additionally, proposed policy 2.5(A), *HIV Screening*, appears to revise the current requirement (2.2.3.3 and 2.2.3.4) for exceptions for cases when HIV testing cannot be completed prior to transplant. In cases involving non-renal organs, current policy allows the transplantation of an organ which has not been tested for HIV when an “extreme medical emergency” warrants such action. The proposed rewrite requires the “Host OPO to have initiated an HIV screening.” Again, such revisions appear to go beyond the scope of the plain language.

In proposed policy 1.3 (B), *Variance Applications*, the 75% threshold for affirmative support by the proposed members of a variance (currently in policy 3.4.8.2) has been excluded. Instead the proposed language states “If unanimous support does not exist, the application must include statements explaining the opposition from each participating Member.” The exclusion of the threshold, in our opinion, creates a policy change which should be vetted through the normal policy processes.

Within Section 1.2, *Definitions*, we are concerned that the exclusionary list under *Eligible Donor* creates too much of a prescriptive tone. It states that the potential donor must not have pneumonia or any fungal infection. The intent of the original policy, was to give examples of guidelines that may be a relative contraindication but the proposed rewrite clearly makes a potential donor with pneumonia ineligible.

These are but a few of the drafted provisions that are not appropriately “translated” and are included in the Policies Plain Language Rewrite.

For these reasons, and others, we oppose this policy proposal and respectfully request that the OPTN refrain from adopting the Policies Plain Language Rewrite in its present form. If you wish, we can provide a more detailed review with specific recommendations. Thank you for the opportunity to comment on this proposal. Please do not hesitate to contact me or Kim Gifford, ASTS Executive Director, if you have any questions or require additional information.

Sincerely yours,

A handwritten signature in blue ink, appearing to read 'Kim Olthoff', with a stylized flourish at the end.

Kim M. Olthoff, MD
President