



MAR 14 2019

Sue Dunn, President
Brian Shepard, Executive Director
Organ Procurement and Transplantation Network
United Network for Organ Sharing
P.O. Box 2484
Richmond, VA 23218

Dear Ms. Dunn and Mr. Shepard:

On February 13, 2019, the Department of Health and Human Services (HHS) received a letter from the law firm of Jones Day (See Enclosed) concerning the Organ Procurement and Transplantation Network's (OPTN) December 2018 liver allocation policy. Jones Day represents 10 liver transplant centers and requests that HHS take immediate action to "direct the OPTN to set aside the policy approved by the OPTN Board of Directors on December 3, 2018 (the Acuity Circles Policy) and further direct the OPTN to work expeditiously to develop a new, lawful policy."

HHS considers this letter to be a critical comment under the National Organ Transplant Act of 1984, as amended (NOTA), and the final rule governing the operation of the OPTN (OPTN Final Rule) as described in 42 U.S.C. 274(c); 42 C.F.R. § 121.4(d). Under the OPTN Final Rule, "[t]he Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices." HHS seeks the OPTN's views on the issues raised in the critical comment.

Since the Acuity Circles Policy was approved by the OPTN Board of Directors, HHS has also received other correspondence, including correspondence from many Members of Congress, concerning the Acuity Circles Policy (See Enclosed).

To assist HHS in its consideration of the critical comment from Jones Day sent on February 13, 2019, please provide the OPTN's views on the new Acuity Circles Policy in light of the information contained in the critical comments, including whether and how the new policy complies with the requirements of NOTA and the OPTN Final Rule, including 42 C.F.R. § 121.8 and 42 C.F.R. § 121.4(a)(3). Specifically, in light of the critical comment, HHS is seeking the OPTN's views on the Acuity Circles Policy adopted by the OPTN Board in relation to the OPTN's consideration of and conclusions concerning the following: (1) the cumulative impact of the policy on socioeconomic inequities, in light of 42 C.F.R. § 121.4(a)(3); (2) patient access to transplantation per 42 C.F.R. § 121.8(a)(5); (3) the predicted number of liver transplants and deaths under this policy; and (4) the use of median model for end-stage liver disease score at transplant. In addition, please respond to the discussion of the OPTN's public comment process as set forth in the critical comment. We also welcome the OPTN's views on any other issues raised in the critical comment.

In addition, please provide the OPTN's response to the issues raised in the other letters enclosed and described above.

This request does not mandate that the OPTN reach any particular conclusions.

I am copying the Chronic Disease Research Group, the contractor that operates the Scientific Registry of Transplant Recipients (SRTR), on this letter and expect that the OPTN will coordinate with the SRTR as necessary to develop the OPTN's response.

We recognize that the OPTN's evaluation of these comments may likely take additional time beyond April 30, 2019, the implementation date of the new Acuity Circles Policy. If such is the case, please advise us as to the length of time beyond April 30, 2019, that OPTN anticipates for this further review and evaluation. Given that my role as the HRSA Administrator is one of oversight, I will review the OPTN's comments in light of the requirements of NOTA and the OPTN Final Rule.

Sincerely,

A handwritten signature in cursive script that reads "George Sigounas".

George Sigounas, MS, Ph.D.
Administrator

Enclosures

cc: Bertram Kasiske, Project Director and
Jon Snyder, Director of Transplant Epidemiology
Chronic Disease Research Group