DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

June 8, 2018

Yolanda Becker, MD
President
Organ Procurement and Transplantation Network
Director, Kidney & Pancreas Transplant
The University of Chicago Medicine
5841 S. Maryland Avenue
Chicago, IL 60637

Dear Dr. Becker:

As you are aware, the Department of Health and Human Services (HHS) received the attached letter concerning the Organ Procurement and Transplantation Network's (OPTN) current and revised Liver Allocation Policy[1] on May 30, 2018. Counsel representing several liver transplant candidates in the New York Area asks HHS to take immediate action and direct the OPTN to set aside those portions of the revised OPTN Liver Allocation Policy "that require livers from deceased donors to be allocated to candidates based on arbitrary geographic boundaries instead of medical priority," noting that his clients can seek immediate judicial relief as an alternative. The letter criticizes the use of donor service areas (DSAs) and OPTN regions in the revised OPTN Liver Allocation Policy. The letter also criticizes as arbitrary and contrary to law aspects of the revised Liver Allocation Policy in which the new National Liver Review Board (NLRB) is to use median MELD in DSAs to calculate the exception points assigned to transplant candidates.

We consider 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 Organ Procurement and Transplantation Network (OPTN final rule). 42 U.S.C. 274(c); 42 CFR 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." We are seeking comments of the OPTN on this critical comment letter, as described more fully below.

As general background, the OPTN Board of Directors is required to develop "policies for the equitable allocation of cadaveric organs among potential recipients" that, among other factors, shall be based on sound medical judgment; shall seek to achieve the best use of donated organs; shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement; and shall not be based on the candidate's place of residence or place of listing, except to the extent required by

[1] I understand that changes to the OPTN Liver Allocation Policy approved by the OPTN Board of Directors in June and December 2017 have not yet been implemented, pending computer programming.

paragraphs (a)(1)–(5) of this section. 42 CFR 121.8(a)(1), (2), (5), and (8). In addition, "[a]llocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section" through several articulated performance goals, including "[d]istributing organs over as broad a geographic area as feasible under paragraphs (a)(1)–(5) of this section, and in order of decreasing medical urgency." 42 CFR 121.8(b)(3).

HHS relies on the expertise of the OPTN and its members, which includes stakeholders that are part of the transplant community and other interested members of the public, to consider and balance these factors as organ allocation policies are developed and revised.

The OPTN has identified the use of geography in OPTN organ allocation policies as an area of concern with respect to compliance with the OPTN final rule.

In November, 2012, the OPTN Board adopted the following resolution regarding geography in organ allocation:

> The existing geographic disparity in access to allocation of organs for transplants is unacceptably high. The Board directs the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013. The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represent patient outcome. The Board requests that optimized systems utilizing overlapping versus non-overlapping geographic boundaries be compared, including using or disregarding current DSA boundaries in allocation.

In 2017, a federal court required that an emergency review be conducted of the OPTN Lung Allocation Policy and its use of DSAs, in connection with litigation filed on behalf of a transplant candidate in New York. In response to the court's directive and to a critical comment filed with the Secretary, HRSA directed the OPTN to conduct an emergency review that included consideration of the use of DSAs in the Lung Allocation Policy and their conformance with the OPTN final rule. The HRSA directive for such a review did not require a specific policy outcome. At the conclusion of such emergency review, the OPTN Executive Committee, acting on behalf of the OPTN Board of Directors, concluded that "a policy that does not depend on DSA as the primary unit of allocation of lungs is more consistent with the OPTN Final Rule than a policy that shares first only within the DSA." *OPTN Executive Committee Report,* pages 2-3 (available at https://optn.transplant.hrsa.gov/media/2398/optn_letter_to_hrsa_20171124.pdf). The OPTN Executive Committee further noted while "some geographic constraints are appropriately considered in lung allocation policy consistent with the [OPTN final rule], . . . [u]pon review of available data and literature, and after consultation with the OPTN/UNOS Thoracic Organ Transplantation Committee (Thoracic Committee), the OPTN Executive Committee determined that the current lung allocation policy contains an over-reliance on DSA as a unit of allocation." Id. The OPTN Executive Committee then approved interim changes to the Lung Allocation Policy by unanimous vote.

The OPTN has also recently created an Ad Hoc Geography Committee to review the use of geography in allocation policies, which I commend.

To assist HHS in its consideration of the critical comment received on May 30, I am seeking the views of the OPTN on the issues raised. Please provide the OPTN's views on whether the following aspects of the revised OPTN Allocation Policy are consistent with the requirements of NOTA and the OPTN final rule, including 42 CFR 121.8(a)(8): (1) using DSAs as units of

allocation; (2) using OPTN regions as units of allocation, alone or in combination with a nautical circle originating from donor hospitals; (3) using proximity points in relation to DSAs; and (4) using median MELD in DSAs in granting exception points to transplant candidates. Given the OPTN Executive Committee's conclusions with respect to the use of DSAs in the Lung Allocation Policy in 2017, the OPTN should provide its rationale if it concludes that the use of DSAs in any of the above-described aspects of the revised Liver Allocation Policy is distinguishable and that their use with respect to liver allocation furthers the requirements of the OPTN final rule. This request does not mandate that the OPTN reach any particular conclusions.

Please send your comments to me, with a copy to Cheryl Dammons, Associate Administrator of HRSA's Healthcare Systems Bureau, by June 25, 2018. Given that my role as 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,

George Sigounas, MS, PhD
Administrator

Attachment