



Rockville, MD 20857

Sent via FedEx and Email

Nov 24 2017

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:

On November 21, 2017, and on behalf of the Department of Health and Human Services (HHS), I notified the Organ Procurement and Transplantation Network (OPTN) that HHS was directing the OPTN to initiate an emergency review of the Lung Allocation Policy, to respond to a critical comment submitted by attorneys for a lung-transplant candidate on November 16, 2017, and in compliance with a Court Order of the United States District Court for the Southern District of New York dated November 20, 2017, issued in connection with a lawsuit filed on behalf of the same transplant candidate on November 19, 2017. Our instruction did not direct the OPTN to reach a particular conclusion, but did mandate that the OPTN consider the current Lung Allocation Policy, particular those aspects raised in the pending lawsuit, in light of the requirements of the OPTN final rule.

As you are aware, in the lawsuit the plaintiff sought a temporary restraining order (TRO), a preliminary injunction and a permanent injunction to require the Acting Secretary of Health and Human Services to enjoin HHS and the OPTN from applying the aspect of the Lung Allocation Policy that uses the donation service area (DSA) as a primary unit of allocation for deceased adult lungs. Upon reviewing the motion and after hearing arguments from plaintiff and the government, the Court issued an Order denying the plaintiffs application for a temporary restraining order, but ordering HHS "to initiate an emergency review of the current [lung] allocation policy and file a written report by 5:00 p.m. on November 28, 2017, as to whether and to what extent the [OPTN lung allocation] policy will be changed, and a timetable for the implementation of any change(s)." Holman v. Secretary of HHS, Civ. Action No. 17-cv-09041, S.D.N.Y. (filed November 19, 2017).

On November 21, 2017, attorneys for the plaintiff filed an emergency motion for a temporary restraining order and injunctive relief pending appeal with the United States Court of Appeals for the Second Circuit (Second Circuit). On November 22, 2017, the government filed an opposition to that Motion. That evening, the Court contacted the attorneys from the U.S. Attorney's Office who are representing HHS in the litigation, and asked whether it would be possible for HHS to accelerate its reporting deadline from Tuesday, November 28, to Friday, November 24. Shortly thereafter, the Court ordered HHS "to file a report on the Organ

Procurement and Transplantation Network's ('OPTN') expedited review of its organ allocation policy as it applies to Appellant" by Friday, November 24, 2017, at 3:00 pm.

In order to comply with the Second Circuit's Order, and in response to HRSA's request, I understand the OPTN Executive Committee, acting on behalf of the OPTN Board of Directors, met on November 22, 2017, to deliberate and consider changes to the OPTN Lung Allocation Policy. At that meeting, I understand the OPTN Executive Committee reviewed the criteria used for lung allocation policy, and the rationale for utilizing DSAs as the primary unit of allocation of lungs in the classifications established in the Lung Allocation Policy, consistent with the requirements of the OPTN final rule, as compared with a policy that would not depend on DSAs as the primary unit of allocation of lungs.

Subsequently, I understand the OPTN Executive Committee met on November 24, 2017, to further consider these issues and to vote on proposed policy changes. At the conclusion of that meeting, the OPTN provided me with a Report on the Review of Lung Allocation Policy by the OPTN/United Network for Organ Sharing (UNOS) Executive Committee ("OPTN Executive Committee Report"). The OPTN Executive Committee Report provides that 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." The OPTN Executive Committee further 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 at pages 2-3.

Based on its emergency review, the OPTN Executive Committee voted unanimously to propose changes to the Lung Allocation Policy to remove the use of DSAs as units of allocation. Specifically, for the allocation of lungs from adult donors, the OPTN Executive Committee recommended replacing the use of DSAs as the first unit of lung allocation with a 250 nautical mile circle, measured from the donor hospital. OPTN Executive Committee Report, proposed changes to Policy 10.C.4, Table I 0-9, Classifications 1 through 6. Per the OPTN Executive Committee's Report, "[a] 250 mile [circle] promotes broader geographic access to lungs while reducing the risk of unintended consequences arising to candidates in certain medical or demographic categories that have not yet been modeled." OPTN Executive Committee Report at page 3. I understand that the UNOS Research Department did analysis concerning the effects of a 250 nautical mile circle unit of allocation for lungs. For the allocation of lungs from pediatric donors, the OPTN Executive Committee recommended replacing DSAs with a 250 nautical mile circle. OPTN Executive Committee Report, proposed changes to Policy 10.C.4, Table 10-10, Classifications 1 through 8. Other units of allocation for lungs would not be modified.

Pursuant to 42 CFR 121.4(d), I have sought and considered the OPTN's views on the critical comment described above, and have considered the comments in light of the National Organ Transplant Act of 1984, as amended (NOTA), and the OPTN final rule. In addition, consistent with HHS's role of oversight of the OPTN, I have concluded that the actions taken by the OPTN

Executive Committee are responsive to the instructions issued in my letter of November 21, 2017.¹

Please proceed with implementing the OPTN Executive Committee's recommended changes to the OPTN Lung Allocation Policy, including the necessary computer reprogramming. As you know, the OPTN Executive Committee advises that the necessary programming to effect the changes recommended to the Lung Allocation Policy will be ready for implementation nationwide on November 25, 2017.

The changes to this policy approved by the OPTN Executive Committee will be considered an interim change, taking effect immediately, upon completion of the programming. The OPTN should proceed with a full solicitation of comments from the OPTN membership and the public on this policy change and the public should specifically be asked to consider the interim policy and alternative policies in light of the requirements of the OPTN final rule. Within 1 year of the effective date of the interim policy, the OPTN Board of Directors, upon review of the Lung Allocation Policy in light of the requirements of the OPTN final rule, and in consideration of the public comments and feedback received, shall take a final action to either: (1) approve this interim policy; or (2) approve any other changes to the OPTN Lung Allocation Policy it believes to be more consistent with the requirements of the OPTN final rule.

We appreciate the OPTN's expedited review and deliberation of these critical policies that serve patients, and implement the NOTA and the OPTN final rule.

Sincerely,



George Sigounas, MS, Ph.D.
Administrator

Attachments:

- 1) Letter to OPTN of 11/21/2017
- 2) OPTN Executive Committee Report of 11/24/2017

¹ This letter does not constitute a Secretarial approval of an OPTN rule or requirement for purposes of § 1138 of the Social Security Act. See 42 U.S.C. § 1320b-8; 54 Fed. Reg. 51802 (Dec. 18, 1989).