DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

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Sent via FedEx and Email

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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, attorneys representing an adult transplant candidate filed a critical comment with our Department on November 16, 2017, requesting that HHS take immediate action and direct the Organ Procurement and Transportation Network (OPTN) to set aside those portions of the OPTN Lung Allocation Policy, Policy 10, "that require donor lungs to first be made available to candidates within [organ procurement organizations'] Donor [sic] Service Areas (DSAs) irrespective of a candidate's medical priority."

On November 19, 2017, this transplant candidate filed a lawsuit in the United States District Court for the Southern District of New York. The complaint argued that the use of organ procurement organization (OPO) donation service areas (DSAs) as the first unit of allocation for lungs from deceased adult donors under the OPTN Lung Allocation Policy (Lung Allocation Policy) is in direct contravention of NOTA, the OPTN final rule, and sound medical judgment. The complaint further argues that the allocation policy discriminates against people such as the plaintiff based on geography and not on medical priority in contravention of the OPTN final rule. 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 DSA as a primary unit of allocation for deceased adult lungs. Specifically, the plaintiff seeks removal of Classifications 1 through 6 in the Lung Allocation Policy, Table 10-9, such that the first unit of allocation will be Zone A.

Judge Swain of the United States District Court for the Southern District of New York held a hearing considering the plaintiffs request for a TRO on November 20, 2017. At the conclusion of the hearing, the Court denied the plaintiffs application for a TRO, but ordered 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. l 7-cv-09041, S.D.N.Y. (filed November 19, 2017).

As the Administrator of the Health Resources and Services Administration (HRSA), and on behalf of the Department of Health and Human Services, I am directing the OPTN to initiate an emergency review of the Lung Allocation Policy, in accordance with that Court Order and as a first step in responding to the critical comments letter. Specifically, I am directing the OPTN to review the use of DSAs in the Lung Allocation Policy in accordance with the requirements of the OPTN final rule. By 10:00 a.m. ET. on November 27, 2017, the OPTN Board of Directors (or the OPTN Executive Committee, as appropriate) must inform HHS whether the use of DSAs in the Lung Allocation Policy is consistent with the requirements of the OPTN final rule. Because the plaintiffs in the above-described case asked the Court to order HHS to disregard Classifications I through 6 of the Lung Allocation Policy, described in Policy 10.C.4, Table 10-9, the OPTN's findings should explain whether the use of those classifications is more consistent with the requirements of the OPTN final rule than an alternative policy in which Classifications 1 through 6 are removed (in which Zone A would be the first unit of allocation for lungs from deceased adults). Any report from the OPTN should include the OPTN's rationale for its conclusions, consistent with the requirements of the OPTN final rule.

If the OPTN, at the conclusion of this expedited review, determines that changes should be made to the Lung Allocation Policy, the OPTN must: (1) describe to what extent and how it proposes that the Lung Allocation Policy be modified based on the OPTN's expedited review; and (2) provide a timetable for implementing such changes, including the programming of its computers to allocateorgans.

This expedited review should be conducted consistent with the OPTN Board's obligations, including developing "[p]olicies for the equitable allocation of cadaveric organs in accordance with [42 CFR 121.8]." 42 CFR 121.4(a)(l). Specifically, the OPTN Board of Directors is charged with developing, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of deceased donor organs among potential recipients. As required by regulation, such allocation policies:

> (1) Shall be based on sound medical judgment;
> (2) Shall seek to achieve the best use of donated organs;
> (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);
> (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
> (5) 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;
> ....
> (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(l)-(5) of this section.

42 CFR 12l.8(a). In addition, "[a]llocation policies shall be designed to achieve equitable allocation of organs among patients consistent with [121.8(a)] through several 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 12l.8(b)(3).

While the OPTN policy development process is generally prescribed by the requirements set forth in 42 CFR 121.4(b), the process I am directing you to undertake in this letter is different due to the filing of a critical comment in this case and the directive to HHS set forth in a Court order. As noted above, a transplant candidate has filed a critical comment pursuant to 42 CFR 121.4(d). Pursuant to that section:

> The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the issues related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risks to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and [the OPTN final rule] and may consult with the Advisory Committee on Organ Transplantation established under 121.12. After this review, the Secretary may:
>
> (1) Reject the comments;
> (2) Direct the OTPN to revise the policies or practices consistent with the Secretary's response to the comments; or
> (3) Take such other action as the Secretary determines appropriate.

42 CFR 121.4(d).

In addition, the above-described Court order mandates that HHS report to the Court by November 28, 2017, as to whether the Lung Allocation Policy will be changed. Given the nature of the relief sought by the plaintiff, the Court expects HHS to report on whether DSA as a primary unit of allocation will be changed in the Lung Allocation Policy.

To the extent that it is possible given this very brief timeframe, we encourage the OPTN Board to consult with relevant entities within the OPTN (e.g., the Thoracic Committee and/or its Lung Subcommittee) and to solicit feedback from the public (e.g., through a conference call). I understand that the issue of whether to replace the DSA as a primary unit of allocation was previously subject to the full OPTN policy-making process, including the solicitation and consideration of public comments, in the context of pediatric lung transplant candidates and led to policy changes adopted by the OPTN Board.[1] I understand further that proposals were submitted to the Executive Committee in 2015 and 2016 to consider policy changes for broader sharing of lungs from deceased adult donors.

Please send your response to me, with a copy to Cheryl Dammons, Associate Administrator of HRSA's Healthcare Systems Bureau. As HRSA Administrator, my role is one of oversight. I am tasked with ensuring that OPTN's policies are consistent with the National Organ Transplant

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1 In 2015, the OPTN solicited public comment on a change of OPTN policy that would result in the DSA being removed as the primary unit of allocation for lungs from pediatric donors and replaced with the combination of the DSA, Zone A and Zone B. Per the Lung Allocation Policy, Zone A includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA and Zone B includes all transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA. The OPTN Board approved this change to the Lung Allocation Policy in December 2015.

Act and the OPTN final rule. Accordingly, I will review the OPTN's response for conformity with the Act and the rule.

We appreciate the efforts of the OPTN to assist HHS in responding to the critical comment and the court's order in a manner that best serves all patients consistent with the OPTN final rule. This is an issue of critical importance, and the expedited review that I am directing you to engage in will inform the response that HHS will submit to the court and that the court will consider in light of plaintiffs pending request for a preliminary and permanent injunction.

Sincerely,

George Sigounas, MS, Ph.D.
Administrator

Attachments

1) Critical Comments to the Secretary Dated 11/16/2017

2) Complaint filed 11/19/2017

3) Court order of 11/20/2017