DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

JUL 31 2018

Ms. Sue Dunn, RN, BSN, MBA
President
Organ Procurement and Transplantation Network
Director, Kidney & Pancreas Transplant
The University of Chicago Medicine
5841 S. Maryland Avenue
Chicago, IL 60637

Dear Ms. Dunn:

This letter addresses a critical comment[1] dated May 30, 2018 (Attachment A) and follows a Health Resources and Services Administration (HRSA) letter, dated June 8, 2018, seeking comments from the Organ Procurement and Transplantation Network (OPTN) on the critical comment (Attachment B) and the OPTN' s response, dated June 25, 2018 (Attachment C).

Through this letter, I share HRSA's determination that the OPTN has not justified and cannot justify the use of donation service areas (DSAs)[2] and OPTN Regions[3] in the current liver allocation policy and the revised liver allocation policy approved by the OPTN Board of Directors (OPTN Board) on December 4, 2017 under the HHS final rule affecting the OPTN ("OPTN Final Rule"). This letter directs further OPTN action consistent with HRSA' s oversight role.

The critical comment, filed on behalf of several liver transplant candidates, criticizes the use of DSAs and OPTN Regions in the current and revised OPTN liver allocation policies, asks HHS to immediately direct the OPTN to set aside those portions of the revised liver allocation policy

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[1] Any interested individual or entity may submit to the Secretary critical comments concerning the manner in which the OPTN is carrying out its duties. 42 U.S.C. § 274(c); 42 CFR 121.4(d). Prior to his review, "[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." 42 CFR 121.4(d). The Secretary is charged with considering the comments in light of NOTA and the OPTN final rule and may: "(1) Reject the comments; (2) Direct the OPTN 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).

[2] DSAs are the designated service areas assigned to each organ procurement organization (OPO) certified by the Centers for Medicare & Medicaid Services, HHS (CMS) for the purpose of procuring deceased donor organs. The 58 DSAs in the United States vary widely in geographic size and population.

[3] The OPTN is divided into 11 OPTN Regions that vary in geographic size and population. All references to Regions in this letter are to the 11 OPTN Regions as currently constituted. Using other regional units as part of organ allocation policies is not foreclosed under the OPTN final rule as long as the regulatory requirements are satisfied.

"that require livers from deceased donors to be allocated to candidates based on arbitrary geographic boundaries instead of medical priority" and to "follow a zone-based distribution consistent with both the law and how other organs (e.g., lungs and hearts) are distributed." See Attachment A.

The OPTN is required to establish "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list ..." and shall "assist [OPOs] in the nationwide distribution of organs equitably among transplant patients." 42 U.S.C. §§ 274(b)(2)(A)(ii); 274(b)(2)(D) (this latter language, enacted in 1990, differs from the original statutory language that contemplated DSAs as the initial unit of organ distribution). Under the OPTN final rule, the OPTN Board is required to develop "policies for the equitable allocation of cadaveric organs among potential recipients" that:

> (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;
> (6) Shall be reviewed periodically and revised as appropriate;
> (7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
> *(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.*

42 CFR 121.8(a) (emphasis added). Thus, a policy that relies upon a candidate's place of listing can only meet the regulatory requirements to the extent such reliance is required by section 121.8(a)(l)-(5). In addition, "[a]llocation policies shall be designed to achieve equitable allocation of organs among patients consistent with [42 CFR 121 .8(a)]" through several articulated performance goals, including "[d]istributing organs over as broad a geographic area as feasible under [42 CFR 121.8(a)(l)-(5)], and in order of decreasing medical urgency." 42 CFR 121.8(b)(3).

The OPTN has other policymaking mandates. See, e.g., 42 CFR 121.4. As some in the transplant community have noted, the OPTN is required to develop policies on matters including those that reduce inequities resulting from socioeconomic status, including "[r]eform or allocation policies based on an assessment of their cumulative effect on socioeconomic inequities." 42 CFR 121.4(a)(2)(iv).

Despite numerous opportunities over the course of many years, the OPTN Board has failed to provide a justification as to how DSAs and Regions meet the requirements of the OPTN final rule, including the requirement described at 42 CFR 121.8(a)(8). The OPTN has identified the

use of geography in OPTN organ allocation policies as a general area of concern with respect to compliance with the OPTN final rule.[4] More specifically, the OPTN Board has repeatedly reached the conclusion that DSAs and Regions are not the best means of allocating livers. In its response to the critical comment described above, the OPTN opined that some geographic limits are appropriate and asserted that improvements are reflected in the revised (but not yet implemented) liver allocation policy as compared with the current liver allocation policy. Nevertheless, the OPTN concluded that "DSAs are not a good proxy for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs as drawn today are not rationally determined in a manner that can be consistently applied equally, that "moving to a framework that utilizes a more consistent and direct measure of distance to restrict distribution of organs as required to reduce organ wastage and promote system efficiency" is important, and that "like DSAs, OPTN Regions are an imperfect substitute for proximity between the donor and candidates." See Attachment C.

HRSA finds that geographic constraints may be appropriate if they can be justified in light of the regulatory requirements, but that DSAs and Regions have not and cannot be justified under such requirements. On this basis, the OPTN Board is directed to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant with the OPTN final rule. HRSA is not directing any particular policy outcome or allocation scheme. HRSA continues its longstanding practice of relying 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 address the requirements of the OPTN final rule as organ allocation policies are developed and revised.

The OPTN Board is directed to consider and explain how any liver allocation policy approved by the OPTN satisfies the requirements of the OPTN final rule. If some form of geographic limitation is incorporated, the OPTN Board should provide its written rationale, together with supporting evidence, explaining how any such limitation is justified and required by 42 CPR 121.8(a)(8), including concerning the size and shape of any geographic units selected. Because the OPTN final rule permits geographic limits based on transplant candidates' place of residence or listing only *to the extent required by* one of the factors described in 42 CFR 121.8(a)(l)-(5), the OPTN Board should provide its rationale as to how any specific geographic unit of distribution is justified by one of those regulatory factors.

HRSA has received correspondence from several parties opposing broader geographic sharing, based on an assertion that this would increase or maintain socioeconomic inequities, and a lawsuit filed by the author of the critical comment similarly raises concerns about socioeconomic inequities in access to transplantation alleged to arise from the current and revised liver allocation policies and current practices. None of these arguments or other information HRSA has considered alters our determination of the impermissibility of using DSAs and Regions in liver allocation policy. Neither DSAs nor Regions were created to allocate organs equitably or optimally distributing donated organs, let alone to improve transplant candidate access to transplantation or addressing the cumulative effects of allocation policies on socioeconomic inequities. None of the arguments or information that have come to HRSA' s attention provided HRSA with any evidence that a policy that uses DSAs and Regions, as compared with a policy

[4] See HRSA letter dated June 8, 2018 (Attachment B) (describing the November 2012 OPTN Board resolution finding "[t]he existing geographic disparity in access to allocation of organs for transplants is unacceptably high" and directing action by organ-specific committees, and describing the 2017 decision of the OPTN Board to replace DSAs with 250 mile concentric circles from donor hospitals as more consistent with the OPTN final rule in response to a Court directive and an emergency OPTN review of the lung allocation policy).

that uses any alternate units of distribution, decreases the cumulative effect of the policy on socioeconomic inequities on all transplant candidates on the national OPTN liver waiting list. The OPTN Board would also have to demonstrate that continued reliance on DSAs or Regions is required by factors described in 42 CFR 121 .8(a)(1)-(5). Regardless, any review of a proposed allocation policy would not be limited to such considerations and would require an assessment under all of the regulatory requirements outlined in the OPTN final rule. The OPTN Board shall also consider the effects of any proposed policies on their "cumulative effect on socioeconomic inequities," as well as other factors described in NOTA and the OPTN final rule, including the unique needs of children. See 42 U.S.C. § 274; 42 CFR 121.4, 121.8.

The OPTN is also directed to revisit variances in liver allocation. Per 42 CFR 121.8(g), variances are time-limited "experimental policies that test methods of improving allocation, [which] shall be accompanied by a research design and include data collection and analysis plans." Existing variances may be retained, modified, or eliminated, and all remaining variances must meet the regulatory requirements. The OPTN Board may also choose to adopt new variances to test methods of improving liver allocation. Given that all variances are to be developed by 42 CFR 121.4, any changes to existing variances or new variances should also go through public comment before their approval.

The OPTN may also implement transition patient protections. See 42 CFR 121.8(d)(1) (providing that when the OPTN revises organ allocation policies, it shall consider whether to adopt transition procedures that would treat people on the waiting list and await transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies). Of course, the OPTN will also have opportunities in the future to refine, modify, and improve any OPTN liver allocation policy.

Consistent with the OPTN final rule, any proposed policies should be made available for public comment, and such comments must be considered by the OPTN Board before the adoption of any policy. The OPTN Board may also consider previously proposed policies, modeling, and public comments submitted in the past concerning such proposed policies. If appropriate, the OPTN may wish to solicit additional public comments concerning certain proposed policies that were previously circulated for public comment. Consistent with the OPTN' s practice, available data and scientific modeling from the Scientific Registry for Transplant Recipients (SRTR) should inform decisions made by the OPTN Board.

The directives contained in this letter align with and support the plan that the OPTN Board has already committed to based on its assessment of the current and revised liver allocation policies. Based on the OPTN' s findings, the OPTN Board has committed to adopting a new liver allocation policy that no longer uses DSAs or Regions. The OPTN Board has developed a plan, which includes statistical modeling and public comment, to adopt a new policy at the December 2018 OPTN Board meeting. See Attachment C.

Given the imbalance between the livers available for transplantation and those in need of liver transplants, some transplant candidates will receive priority for organ offers and others will not, regardless of which organ allocation policy is in effect. We understand that liver allocation policy is complicated and that there is an absence of unanimity among transplant stakeholders and the public concerning the optimal methods of liver allocation. It appears that achieving consensus for a new liver allocation policy may not be possible. Such consensus is not required under the OPTN final rule and should not be a barrier to adopting a liver allocation policy that complies with the OPTN final rule.

This letter directs the OPTN Board to approve a liver allocation policy, consistent with the terms described in this letter and the OPTN final rule, by its December 2018 meeting.[5] If the OPTN Board fails to adopt a liver allocation policy that eliminates DSAs and Regions and that is otherwise consistent with the requirements of the OPTN final rule, the Secretary may exercise further options or direct further action consistent with his authority under 42 CFR 121.4(d).

Because the problems associated with DSAs and Regions are not limited to liver allocation, HRSA has considered their use in other allocation policies.[6] For the same reasons described above concerning liver allocation, HRSA finds that the use of DSAs and Regions in all other (non-liver) organ allocation policies has not been and cannot be justified under the OPTN final rule. This finding is aligned with those made by the OPTN Board and with the OPTN' s existing plans for future policymaking. The OPTN has committed to eliminating the use of DSAs and Regions from all OPTN allocation policies. The OPTN Board recently approved circulating for public comment several frameworks for organ allocation (formulated by the Ad Hoc OPTN Committee on Geography) that would eliminate DSAs and Regions from all organ allocation polices. Also, the Executive Committee of the OPTN Board has directed that all OPTN committees, beginning with the Liver Committee, prioritize allocation projects to remove DSAs and Regions from all organ allocation policies. The OPTN is directed to submit a detailed report by August 13, 2018, for review by HRSA outlining the OPTN' s plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies, for ensuring that such policies satisfy the requirements of the OPTN final rule (including the OPTN's plans for ensuring that the OPTN Board provides an appropriate rationale), and the steps and timelines that will be followed.

As stewards of the national resource of donated organs, we thank you for your efforts to improve national organ allocation to best serve those in need of this lifesaving procedure.

Sincerely,

George Sigounas, MS, Ph.D.
Administrator

Attachments

[5] In light of this directive, OPTN resources should not be utilized on computer programming or other implementation of those aspects of the revised liver allocation policy that relies upon DSAs or Regions.

[6] This table reflects the use of DSAs and Regions in non-liver OPTN allocation policies:

Organ allocation policy	Uses DSAs	Uses Regions
Lungs		
Hearts	✓	
Kidneys	✓	✓
Pancreata or Kidney-Pancreas	✓	✓
Intestines	✓	✓
Vascularized composite allografts (VCAS)		✓