IN THE MATTERS OF	*	
	*	
MEDSTAR FRANKLIN SQUARE KIDNEY TRANSPLANT SERVICE	*	
	*	BEFORE THE MARYLAND
Docket No. 17-03-2405	*	HEALTH CARE
	*	
-and-	*	COMMISSION
	*	
MEDSTAR FRANKLIN SQUARE LIVER TRANSPLANT SERVICE	*	
	*	
Docket No. 17-03-2406	*	

* * * * * * * * * * * * * *

UNIVERSITY OF MARYLAND MEDICAL CENTER'S MOTION FOR STAY OF CERTIFICATE OF NEED REVIEW OF MEDSTAR HEALTH, INC.'S APPLICATIONS PROPOSING THE ESTABLISHMENT OF LIVER AND KIDNEY TRANSPLANT SERVICES

University of Maryland Medical Center ("UMMC"), by its undersigned counsel and pursuant to COMAR § 10.24.01.10B, submits this Motion for Stay of the Certificate of Need ("CON") reviews of the applications and related materials filed by MedStar Health, Inc. ("MedStar") proposing to establish liver and kidney transplant services at Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center ("MFSMC"). UMMC requests that the Commission defer review of MedStar's applications until the United Network for Organ Sharing approves forthcoming changes to liver allocation policy in December 2018 and kidney allocation policy in December 2019, and require MedStar to update its analyses of its compliance with the applicable State Health Plan chapter and review criteria based on those new policies.

Statement of Interested Party Status

As set forth more fully in UMMC's interested party comments, filed together with this motion, UMMC is an "interested party" in these reviews within the meaning of COMAR § 10.24.01.01B(20) because UMMC is authorized to provide the same services as the applicant seeks to establish, in the same planning region used for purposes of determining need under the State Health Plan.

Introduction

The Commission should stay the review of MedStar's applications to establish liver and kidney transplant programs because the applications and applicable State Health Plan chapter assume the existence of Donation Service Areas for organ procurement ("DSAs") that will soon be obsolete. Current liver and kidney allocation policies will be replaced in December 2018 and December 2019, respectively, with policies that will allocate organs on a larger geographic scale that will look beyond the current, artificial boundary lines of existing DSAs and will prioritize allocution to the most acute adult and pediatric patients.[1] These changes render much of MedStar's analyses of its compliance with the applicable review standards and criteria moot, and undermine MedStar's justification for a new program at MFSMC.

Significantly, under existing allocation policy, MedStar's proposed efforts to create more donor organs in the Baltimore-area DSA would benefit patients waitlisted at UMMC and JHH more than patients waitlisted at MGTI, because MGTI is in a different DSA. Thus, opening a

---

[1] As discussed more fully on the following pages, the UNOS Board of Directors will approve new liver allocation policy by December, 2018 and will implement it by April, 2019. The Board will approve new kidney allocation policy by December 2019, and will implement it thereafter.

program at MFSMC, which is in the same DSA at UMMC and JCC, would increase the benefit of MedStar's Baltimore-area efforts to MedStar patients, assuming those patients join the MFSMC waitlist. Under the forthcoming allocation policy, however, MedStar's efforts to increase the donor organ supply in the Baltimore area would benefit patients waitlisted at MGTI JHH, and UMMC equally, because of the geographic proximity of the hospitals and the removal of artificial DSA boundaries. Simply put, MedStar will not need a program at MFSMC in order for its patients to receive the maximum benefit from its proposed efforts to increase the organ supply in Maryland.

The Commission should defer review of MedStar's applications until new allocation policy is finalized. In addition, because much of MedStar's analyses will be rendered moot by the allocation policy changes, the Commission should require MedStar to submit new analyses regarding whether there is any need for a new transplant program at MFSMC in light of the new allocation policies.

ARGUMENT

I. DONATION SERVICE AREAS WILL SOON BE OBSOLETE FOR KIDNEY AND LIVER ALLOCATION

A. Current Organ Allocation Policy

Organ allocation policy in the United States is governed by the Final Rule issued by the U.S. Department of Health and Human Services ("HHS") and codified at 42 C.F.R. Part 121. The Final Rule establishes a regulatory framework for the structure and operations of the Organ Procurement and Transplantation Network ("OPTN"). 42 C.F.R. Part 121. Within HHS, the Health Resources and Services Administration ("HRSA") oversees organ donation. OPTN is responsible for developing organ transplantation policy in the United States, including how

donor organs are allocated to transplant recipients. Id.; see also COMAR § 10.24.15.03, p. 5-6. HRSA operates the OPTN through a contract with the United Network for Organ Sharing ("UNOS"). Id., p. 6.

UNOS currently divides the United States into 11 regions. Id., p. 7. The OPTN's current organ allocation policy utilizes 58 distinct DSAs within these 11 regions in order to determine who will receive a donor organ. An Organ Procurement Organization ("OPO") operates in each DSA to facilitate organ procurement and transplantation within that service area. HRSA July 31, 2018 Letter to OPTN, attached as Exhibit A, p. 1. Two OPOs provide organ procurement and distribution services in Maryland: the Washington Regional Transplant Community ("WRTC") and the Living Legacy Foundation ("LLF"). COMAR § 10.24.15.03, p. 7-8. MGTI is in the WRTC DSA, and MFSMC is in the LLF DSA.

The geographic boundaries of the DSAs play a significant role in the current allocation of organs because most organs are offered to categories of recipients (based on acuity of illness and organ compatibility, among other factors), first within a DSA, then within a region, and then nationally. Current OPTN liver allocation policy allocates donor livers according to medical priority within a DSA before the organ is offered nationally. UNOS, *Questions and Answers for Transplant Candidates about Liver Allocation*, attached as Exhibit B.

Current OPTN kidney allocation policy is based on several components, including a kidney donor quality metric known as the Kidney Donor Profile Index ("KDPI"), the Expected Post Transplant Survival ("EPTI") of adult candidates, and the Calculated Panel Reactive Antibodies ("CPRA") for sensitized candidates, measuring the likelihood that the recipient and donor would be incompatible. OPTN Policies, Policy 8, Allocation of Kidneys, attached as Exhibit C. OPTN creates different allocation rules for donor kidneys based on KDPI cutoffs.

(Id., Policy 8.5H-K.) In each KDPI range, kidneys are offered first to certain potential recipients (based on CPRA scores and blood type) within an OPO's DSA, then an OPO's region, then nationally, and then the pattern is repeated for an expanded set of potential recipients. Id.

The result of the DSAs and current allocation policies for both livers and kidneys is that patients outside the geographic boundary of a DSA do not have equal access to an organ as a patient of a similar acuity level on the other side of the boundary. For example, a donor organ that becomes available at Anne Arundel Medical Center, which is in the LLF DSA, could under current allocation policy be offered to a patient at UMMC who has a lower but similar range MELD or PELD[2] score than a patient at MGTI, because UMMC is in the LLF while MGTI is in the WRTC. Had the same donor organ become available at Capital Region Health Medical Center, which is just one county away but in the WRTC, the organ would be allocated to the higher acuity patient at MGTI.[3]

B. Forthcoming Changes to Liver Allocation Policy

For the past several years, OPTN has been considering a change in liver allocation policy that would reduce or eliminate reliance on the artificial geographical boundaries of the DSAs. See generally HRSA June 8, 2018 Letter to OPTN, attached as Exhibit D. Prompted by a

---

[2] MELD is an acronym for Model for End-Stage Liver Disease, a model for "prioritizing candidates waiting for liver transplants based on statistical formulas that are designed for predict who needs a liver transplant most urgently." UNOS, *Questions and Answers for Transplant Candidates about Liver Allocation*, E. MELD scores are used for candidates 12 and older. Id. PELD (Pediatric End-Stage Liver Disease Model) scores are used for patients 11 and younger. Id.

[3] This example also demonstrates the underlying motive for MedStar's application – under this scenario, if MFSMC also had a program, the organ would be allocated to the higher acuity MedStar patient, who has access to both waitlists, regardless of whether the organ became available in the LLF or WRTC DSA.

recently-submitted critical comment, which was followed by a lawsuit filed on behalf of several patients on liver waitlists in DSAs with longer-than-average wait times, HRSA directed OPTN to comment on whether certain aspects of current allocation policy, including the reliance on DSAs and regions, were consistent with the OPTN final rule. HRSA June 8, 2018 Letter to OPTN, Exhibit D.

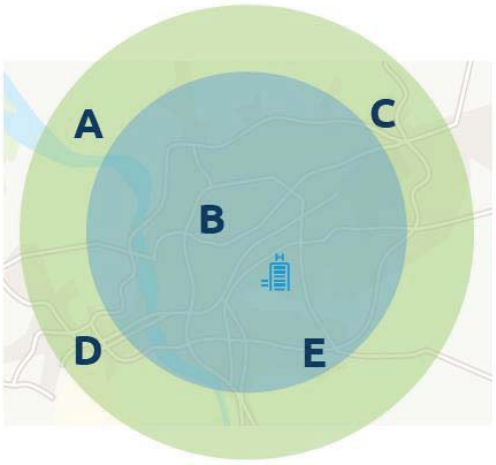
Based on OPTN's response, HRSA found that OPTN "has not justified and cannot justify the use of donation service areas (DSAs) and OPTN Regions in the current liver allocation policy." HRSA July 31, 2018 Letter to OPTN, Exhibit A, p. 1. HRSA noted that under the final rule, OPTN was required to "develop policies for the equitable allocation of cadaveric organs among potential recipients" that, among other things, "[s]hall not be based on the candidates' place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."(Id., p. 2, citing 42 C.F.R § 121.8(a)). HRSA ultimately directed OPTN to "approve liver allocation policy, consistent with the terms described in this letter and the OPTN final rule, by its December 2018 meeting." Id., p. 4. OPTN confirmed in its August 13, 2018 response that its Board will approve new liver allocation policy in December 2018, and implement it by April, 2019. August 13, 2018 UNOS Letter regarding Plan for Amending Organ Allocation Policies, attached as Exhibit E.

In compliance with HRSA's directive, OPTN has taken affirmative steps to change its liver allocation policy to eliminate the use of DSAs. On July 19, 2018, OPTN submitted to the Scientific Registry of Transplant Recipients ("SRTR") a request for the evaluation of two proposed frameworks for liver redistribution. See OPTN Committee Data Analysis Request Form, attached as Exhibit F. These frameworks—called "Acuity Circles" and "Broader 2-Circle Distribution"—eliminate reliance on DSAs and instead allocate livers to transplant candidates

based upon both (1) the candidate's MELD or PELD score; and (2) a geographic zone not defined by artificial boundaries but, rather, measured by the distance in nautical miles of the transplant candidate from the donor hospital. According to both proposed allocation models, patients with higher MELD or PELD scores who are located a certain number of nautical miles from a donor hospital would generally be considered first for a potential transplant, and from there the search for a recipient would expand outward to geographic regions defined by concentric circles of increasingly large radii centered on the donor hospital.

The following figure illustrates, generally, the basic geographic concept of both potential frameworks, depicting concentric circles with increasingly large radii around the donor hospital (depicted as the blue "H" in the graphic). Assuming candidates waitlisted at hospitals A-E are within the same MELD/PELD score ranges, the candidates at transplant hospitals B and E are within the first proximity circle, and would be offered the organ first based on waitlist priority; if declined, candidates waitlisted at hospitals A, C, and D, in the wider, green circle would become eligible.

Figure 1
Representation of Organ Distribution Based on Fixed Distance from the Donor Hospital



Source: OPTN, Public Comment Proposal, Frameworks for Organ Distribution, Exhibit G

The Acuity Circles allocation method involves several acuity cutoffs and three increasingly large geographic circles, after an initial wide circle prioritizing the highest acuity level patients. The OPTN requested that two simulations be run: one using distances of 150 nm, 250 nm, and 500 nm, and one using distances of 150 nm, 300 nm, and 600 nm. The following table defines the Acuity Circles method of allocating livers from deceased, non-cardiac death ("Non-DCD"), liver donors who are at least 18 years old and younger than 70 years old.

Table 1
Allocation of Livers from Non-DCD Deceased Donors, Ages 18-70[1]

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Adult or pediatric status 1A
2	[500/600]nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 37
4	[250/300]nm	MELD or PELD of at least 37
5	[500/600]nm	MELD or PELD of at least 37
6	150nm	MELD or PELD of at least 33
7	[250/300]nm	MELD or PELD of at least 33
8	[500/600]nm	MELD or PELD of at least 33
9	150nm	MELD or PELD of at least 29
10	[250/300]nm	MELD or PELD of at least 29
11	[500/600]nm	MELD or PELD of at least 29
12	150nm	MELD or PELD of at least 15
13	[250/300]nm	MELD or PELD of at least 15
14	[500/600]nm	MELD or PELD of at least 15
15	National	Adult or Pediatric Status 1A
16	National	Pediatric Status 1B
17	National	MELD or PELD of at least 15
18	150nm	MELD or PELD less than 15
19	[250/300]nm	MELD or PELD less than 15
20	[500/600]nm	MELD or PELD less than 15
21	National	MELD or PELD less than 15

Source: OPTN Committee Data Analysis Request Form Exhibit F.

Note 1: The OPTN Data Request Form creates separate allocation tables for other classes of donors, including: donors aged 11 to 17; donors younger than 11 years old; and DCD donors or donors at least 70 years old. OPTN Data Request Form, Exhibit F. This particular table was chosen as representative because most liver donors are non-DCD between the ages of 18 and 70 years old.

The Broader 2-Circle Distribution method of allocating livers involves just two acuity ranges, after an initial wide circle prioritizing the highest acuity level patients. The following table defines this method's allocation of livers from non-DCD, deceased liver donors who are at least 18 years old and younger than 70 years old.

Table 2
Allocation of Livers from Non-DCD Deceased Donors, Ages 18-70

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Adult or pediatric status 1A
2	500nm	Pediatric status 1B
3	250nm	MELD or PELD of at least [35/32]
4	150nm	MELD or PELD of at least 15
5	250nm	MELD or PELD of at least 15
6	500nm	MELD or PELD of at least 15
7	National	Adult or Pediatric Status 1A
8	National	Pediatric Status 1B
9	National	MELD or PELD of at least 15
10	150nm	MELD or PELD less than 15
11	250nm	MELD or PELD less than 15
12	500nm	MELD or PELD less than 15
13	National	MELD or PELD less than 15

Source: OPTN Committee Data Analysis Request Form, Exhibit F, p. 5.

On September 24, 2018, SRTR submitted its analysis of the proposed frameworks for a new liver allocation policy. SRTR, *Analysis Report*, Sept. 24, 2018, Exhibit H. The SRTR report evaluates, among other things, the median allocation MELD at time of transplant, the median transport time, the median transport distance, and the percent of organs flown under the current liver allocation policy as compared to the Acuity Circles and Broader 2-Circle Distribution frameworks. Based on its review of the SRTR report, the OPTN will select a new allocation model to release for public comment, which is scheduled to begin in early October, 2018. Following the December 2018 Board of Directors meeting, OPTN will implement the

allocation policy change. August 13, 2018 UNOS Letter regarding Plan for Amending Organ Allocation Policies, Exhibit E.

C. Forthcoming Changes to Kidney Allocation Policy

Kidney allocation policy changes are also imminent. In its July 31, 2018 letter, HRSA notified the OPTN 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." HRSA July 31, 2018 Letter to OPTN, Exhibit A, p. 5. HRSA further directed the OPTN to "submit a detailed report by August 13, 2018, for review by the Health Resources Services Administration outlining OTPN's plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies." Id.

In its response to HRSA's July 31 letter, OPTN noted that a working committee has been formed to evaluate and propose changes to the kidney allocation policy. Modeling analyses of these proposed changes will be performed by SRTR by the end of 2018, and public comment is scheduled to take place from January to March, 2019. UNOS Letter regarding Plan for Amending Organ Allocation Policies, Aug. 13, 2018, Exhibit E, p. 4. Ultimately, OPTN projects that a final policy change for kidney allocation will be submitted to the OPTN Board for approval in December 2019. Id. at p. 5.

II. THE FORTHCOMING ALLOCATION POLICIES RENDER MOOT MEDSTAR'S JUSTIFICATION FOR ITS PROPOSED PROGRAMS

The State Health Plan Chapter for Organ Transplant Services, COMAR § 10.24.15, defines "the health planning regions for CON review of an application to establish or relocate organ transplant services in Maryland" to be "consistent with the OPO [Organ Procurement Organizations] designations." COMAR § 10.14.15.03, p. 8. Need for a new project is based in

part, on "[t]he ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donation initiatives, and other efforts." 10.24.15.04B(1).

MedStar states that it is the "shortfall of donor organs, and MGTI's ability to increase the supply of donor organs, that forms the basis of MFSMC's case for its proposed liver transplant program." MedStar June 1, 2018 Completeness Response, p. 18. In making this statement, MedStar assumes the existence the soon-to-be-obsolete DSA that covers the Baltimore area. Essentially, MedStar argues that it will create more donor livers within the Baltimore-area DSA, thus benefiting recipients in this DSA. The elimination of DSAs, however, moots this rationale. To the extent MedStar can increase the number of donor livers available in the current Baltimore-area DSA, under the forthcoming liver allocation policy, this increase will benefit all transplant candidates located within, at a minimum, 150 nautical miles of the donor hospital, including those on the waitlist at MGTI, regardless of whether MFSMC has a liver transplant program. Simply put, MedStar need not open a liver transplant program in the Baltimore-area DSA in order to increase the number of donor livers available to that DSA and benefit MedStar patients, because DSAs will soon no longer exist.

In the same way, MFSMC's need argument regarding its proposed kidney transplant program will soon be irrelevant. As MFSMC notes in its CON application for the kidney program, "[v]ery few organs leave the DSA, unless mandated by current . . . OPTN allocation priority." MedStar Kidney Application, p. 47. Within the next 14 months, however, OPTN will significantly transform the kidney allocation framework to remove the current dependence upon the artificial barriers of DSAs.

As described more fully in UMMC's comments on MedStar's applications, the forthcoming changes also undermine MedStar's analysis of its compliance with additional review standards and criteria. For example, MedStar's proposed liver transplant program may no longer comply with the minimum volume standard, COMAR § 10.14.15.04B(2). Because the new liver allocation frameworks will prioritize more adult and pediatric patients at the highest levels of acuity, the result will be more organs going to sicker people over a broader geographic area. See Tables 1-2 supra. MedStar concedes that its proposed program at MFSMC will not treat pediatric or high-risk patients, although MedStar has refused to define what MELD score will be used as a cutoff. MedStar March 1, 2018 Completeness Resp., pp. 13, 35. Under the existing framework, MFSMC patients would be passed over only for higher acuity adult or pediatric patients at UMMC and the Johns Hopkins Hospital. Under either of the proposed allocation framework methods, new donor livers will first be offered to the highest acuity adult and pediatric patients at all hospitals within at least 500 nm of the donor, a much larger population. See Tables 1-2 supra. With this much expanded competition for organ allocation, a new program that does not treat high acuity or pediatric patients may be unable to perform surgeries at a sufficient level for its staff to remain proficient and its program to remain cost effective.

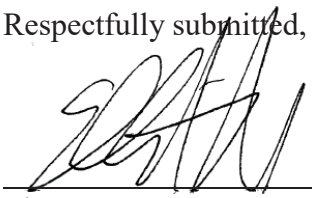
The Commission should defer review of MedStar's organ transplant CON applications until the new allocation policies are established, rather than reviewing the applications under policies that will be outdated before the review will be completed (for the liver program application), or before the new program will be opened (for the kidney program application). Once the new policies are finalized, the Commission could hold a Project Status Conference in order to permit MedStar to modify its applications so that MedStar may update its analyses to

reflect the new allocation policies. Review of the applications under the soon-to-be outdated policies would be an inefficient use of resources and would not further the Commission's purpose of ensuring that proposed programs meet the current and future health care system needs of Maryland residents.

Conclusion

For the reasons set forth above, UMMC respectfully requests that the Commission stay the CON review of MedStar's applications proposing to establish liver and kidney transplant services at MedStar Franklin Square Medical Center.

Respectfully submitted,



Thomas C. Dame
Ella R. Aiken
Hannah L. Perng
Gallagher Evelius & Jones LLP
218 North Charles Street, Suite 400
Baltimore MD 21201
(410) 727-7702

Attorneys for University of Maryland Medical Center

October 15, 2018

Table of Exhibits

Exhibit	Description
A	HRSA July 31, 2018 Letter to OPTN
B	UNOS, *Questions and Answers for Transplant Candidates about Liver Allocation*
C	OPTN Policies, Policy 8, Allocation of Kidneys
D	HRSA June 8, 201 Letter to OPTN
E	UNOS letter regarding Plan for Amending Organ Allocation Policies, Aug. 13, 2018
F	OPTN Committee Data Analysis Request Form
G	OPTN, Public Comment Proposal, Frameworks for Organ Distribution
H	SRTR, *Analysis Report*, Sept. 24, 2018

I hereby declare and affirm under the penalties of perjury that the facts stated in the foregoing document and its attachments are true and correct to the best of my knowledge, information, and belief.

October 15, 2018
Date

Anahita Masoumi, DNP, MBA, RN
Director of Transplant &
VAD Programs

I hereby declare and affirm under the penalties of perjury that the facts stated in the foregoing document and its attachments are true and correct to the best of my knowledge, information, and belief.

October 15, 2018
Date

Scott Tinsley-Hall
Director, Strategy & Market Intelligence

I hereby declare and affirm under the penalties of perjury that the facts stated in the foregoing document and its attachments are true and correct to the best of my knowledge, information, and belief.

October 15, 2018
Date

Rolf Barth, MD
Professor of Surgery

CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of October 2018, a copy of University of Maryland Medical Center's Motion for Stay of Certificate of Need Review of MedStar Health, Inc.'s Applications Proposing the Establishment of Liver and Kidney Transplant Services was sent via email and first-class mail to:

Suellen Wideman, Esq.
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215-2299
suellen.wideman@maryland.gov

Gregory W. Branch, M.D.
Health Officer | Director of Health and Human Services
Baltimore County Health Department
6401 York Road, 3d Floor
Baltimore MD 21212-2130
gbranch@baltimorecountymd.gov

Patricia G. Cameron
Director, Regulatory Affairs – Maryland
MedStar Health
10980 Grantchester Way
Columbia, MD 21044
patricia.cameron@medstar.net

Conor B. O' Croinin, Esq.
Zuckerman Spaeder LLP
100 E. Pratt Street, Suite 2440
Baltimore MD 21202-1031
cocroinin@zuckerman.com

Ella R. Aiken

#641647
006551-0239

EXHIBIT A

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

[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)		✓

EXHIBIT B

TALKING ABOUT TRANSPLANTATION

Questions and Answers for Transplant Candidates about

Liver Allocation

UNITED NETWORK FOR ORGAN SHARING UNOS℠

Questions and Answers for Transplant Candidates about the Liver Allocation System

United Network for Organ Sharing (UNOS) is a non-profit charitable organization that manages the nation's transplant system —known as the Organ Procurement and Transplantation Network (OPTN)— under contract with the federal government. As the OPTN, UNOS helps create and define organ sharing policies that make the best use of donated organs. This process involves continuously evaluating new advances and discoveries so policies can be adapted to best serve patients waiting for transplants.

All transplant programs and organ procurement organizations throughout the country are OPTN/UNOS members and are obligated to follow the policies the OPTN creates for allocating organs.

As part of this process, UNOS developed a system for prioritizing candidates waiting for liver transplants based on statistical formulas that are designed to predict who needs a liver transplant most urgently. The MELD (Model for End- Stage Liver Disease) is used for candidates age 12 and older and the PELD (Pediatric End-Stage Liver Disease Model) is used for patients age 11 and younger.

This document explains the system and how it affects those needing a transplant.

What is MELD? How is it used?

The Model for End-Stage Liver Disease (MELD) is a numerical scale, ranging from 6 (less ill) to 40 (gravely ill), used for liver transplant candidates age 12 and older. It gives each person a 'score' (number) based on how urgently he or she needs a liver transplant within the next three months. The number is calculated by a formula using four routine lab test results:

- bilirubin, which measures how effectively the liver excretes bile
- INR (prothrombin time), which measures the liver's ability to make blood clotting factors
- creatinine, which measures kidney function (Impaired kidney function is often associated with severe liver disease.)
- serum sodium, which measures the severity of conditions such as portal hypertension.

The only priority exceptions to MELD are the categories known as Status 1A and 1B. Status 1A patients have acute (sudden and severe onset) liver failure and a life expectancy of hours to a few days without a transplant. Status 1B is reserved for very sick, chronically ill pediatric patients (age less than 18). Less than one percent of liver transplant candidates are in these categories at any one time. All other liver candidates age 12 and older are prioritized by the MELD system.

A patient's score may go up or down over time depending on the status of his or her liver disease. Most candidates will have their MELD score assessed a number of times while they are on the waiting list. This will help ensure that donated livers go to the patients in greatest need at that moment.

MELD has been shown to rank patients on the waiting list reliably in terms of their short-term risk of death. The MELD formulas are simple, objective and verifiable, and yield consistent results whenever the score is calculated.

What is PELD? How does it differ from MELD?

Candidates age 11 and younger are placed in categories according to the Pediatric End-Stage Liver Disease (PELD) scoring system. Again, a small group of urgent patients may be listed as a Status 1A or 1B. All other candidates in this age range receive priority through PELD.

PELD is similar to MELD but uses some different factors to recognize the specific growth and development needs of children. PELD scores may also range higher or lower than the range of MELD scores. The measures used are as follows:

- bilirubin, which measures how effectively the liver excretes bile
- INR (prothrombin time), which measures the liver's ability to make blood clotting factors
- albumin, which measures the liver's ability to maintain nutrition
- growth failure
- whether the child is less than one year old

As with MELD, a patient's score may go up or down over time depending on the degree of his or her disease severity. Most candidates will have their PELD score assessed a number of times while they are on the waiting list. This will help ensure that donated livers go to the patients in greatest need at that moment.

How are livers allocated?

First, transplant candidates that are not compatible with the donor based on a number of characteristics (blood type, height, weight, etc.) are screened from the match run that determines the order a liver is offered. The remaining candidates on this match run are prioritized based on the following factors:

- the donor's age
- their medical urgency
- their geographical proximity to the donor (local–defined by the Organ Procurement Organization's service area; regional – UNOS has 11 allocation regions in the U.S.; national - all remaining candidates in the nation)

Livers from adult donors are allocated first to the most urgent candidates located in the same region as the donor; Status 1A candidates, followed by Status 1B candidates. The allocation sequence provides broader access to those most in need of a liver (those with scores higher than 35) and those who would receive the most benefit (those with scores higher than 15). Therefore, after regional Status 1A and 1B candidates, liver offers are then made to

- candidates with MELD/PELD scores 35 and higher within the donor's region, with offers first made locally, then regionally (i.e., local 40) regional 40, local 39, regional 39, etc.)
- local candidates with scores greater than 15
- regional candidates with scores greater than 15
- national candidates in Status 1A or 1B
- national candidates with scores greater than 15
- candidates with scores less than 15 locally, regionally, then nationally

If a combined liver-intestine is being offered, candidates waiting for a liver-intestine anywhere in the country may be offered the combination (based on their MELD/PELD score) after local candidates with MELD/PELD scores of 29 or higher.

Partly because pediatric transplant candidates need smaller organs, they will receive priority in the liver offer sequence if the donor is younger than 18.

Liver offer process for donors 0-10 years of age

1. Offers are first extended to all compatible pediatric Status 1A candidates located in the same region as the donor.
2. Next, the liver is offered to the remaining Status 1A candidates across the nation that are 0-11 years old.

3. If the liver has not been accepted yet, it is offered to local adult Status 1A potential transplant recipients then to Status 1A adults in the same region.
4. Next, all pediatric Status 1B candidates in the region receive the liver offer, followed by all candidates 0-11 years old in the region in order of decreasing PELD score.
5. If no one has accepted the liver at this point, it is offered to adolescent (12-17 years old) candidates that are local to the donor and have a MELD score greater than or equal to 15, then to local adults that have a MELD score greater than or equal to 15.
6. That same adolescent/adult MELD score greater than or equal to 15 sequence of offers would then be made to those potential transplant recipients in the region.
7. Following these offers, candidates with a MELD score less than 15 are offered the liver using the same adolescent/adult progression locally, then regionally.
8. If not accepted for any of these patients, the liver is then offered to potential recipients nationwide, with similar pediatric priority and those most urgent patients being offered the liver first.

Is waiting time counted in the sysytem?

Various studies report that waiting time is a poor indicator of how urgently a patient needs a liver transplant. This is because some patients are listed for a transplant very early in their disease, while others are listed only when they become much sicker.

Under the MELD/PELD system with a wide range of scores, waiting time is not often used to break ties. Waiting time will only determine who comes first when there are two or more patients in the same allocation classification with the same MELD or PELD score.

Do MELD and PELD account for all conditions?

MELD/PELD scores reflect the medical need of most liver transplant candidates. However, there may be special exceptions for patients with medical conditions not covered by MELD and PELD. If your transplant team believes your case qualifies for an exception, they may submit information to their regional review board (RRB) and request a higher score. The RRB will consider the medical facts and determine whether or not to grant a higher score.

Is this system likely to change?

Liver allocation policy based on MELD and PELD has changed as transplant professionals have applied and learned from the system, and future changes will likely be required to better meet patients' needs. In fact, this system is designed to be flexible and allow improvements. In transplantation, as in all scientific fields, new studies are taking place all the time to learn how to save more lives and help people live longer and better.

For more information

Start with your doctor or the medical team at your transplant center. They know the most about your specific medical condition and treatment. Don't be afraid to ask questions. It will help you to have a detailed understanding of all your treatment options.

UNOS' Patient Services phone line (888-894-6361) can provide information about the OPTN and UNOS, allocation policy and other resources available to you. Additional information is available online on the following websites:

http://www.transplantliving.org
http://optn.transplant.hrsa.gov
http://www.unos.org
http://www.srtr.org

Our mission is to advance organ availability and transplantation by uniting and supporting its communities for the benefit of patients through education, technology and policy development.

www.unos.org/social

UNOS℠

UNITED NETWORK FOR ORGAN SHARING

700 North 4th Street, Richmond, VA 23219

www.unos.org

104 R3.17

EXHIBIT C

Policy 8: Allocation of Kidneys

8.1 Calculated Panel Reactive Antibody (CPRA)

CPRA is the percentage of donors expected to have one or more of a candidate's indicated unacceptable antigens. CPRA will be calculated automatically when a transplant hospital reports unacceptable antigens to the OPTN Contractor according to *Policy 5.3.A: Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)*.

8.2 Exceptions

8.2.A Exceptions Due to Medical Urgency

Prior to receiving an organ offer from a deceased donor in the same DSA, a candidate's transplant physician may use medical judgment to transplant a candidate out of sequence due to medical urgency.

If there is more than one kidney transplant program in the DSA, then the candidate's physician must receive agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence and must maintain documentation of this agreement in the candidate's medical record.

8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor and the intended recipient cannot be transplanted, the kidney must be allocated according to *Policy 5.9: Released Organs*. When reallocating the kidney, the OPO has the discretion to use either the HLA typing identified by the donor histocompatibility laboratory or the recipient HLA laboratory.

8.3 Kidney Allocation Points

Candidates receive points according to *Tables 8-1* and *8-2* below.

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in *Policy 8.4: Waiting Time*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in *Policy 8.4: Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.H, 8.5.I	1 point
A prior living donor	8.5.H, 8.5.I, or 8.5.J	4 points
Sensitized (CPRA at least 20%)	8.5.H, 8.5.I, or 8.5.J	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	1 point
A zero HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	2 points

*****Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed “homozygous” at that locus.

Table 8-2: Points for CPRA

If the candidate’s CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30

If the candidate's CPRA score is:	Then the candidate receives this many points:
98	24.40
99	50.09
100	202.10

8.4 Waiting Time

8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older

If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following:

1. The candidate's registration date with a measured or calculated creatinine clearance or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

8.4.B Waiting Time for Candidates Registered prior to Age 18

If a kidney candidate is less than 18 years old at the time of registration on the waiting list, then the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered on the waiting list regardless of clinical criteria.
2. The date that the candidate began regularly administered dialysis as an ESRD patient in a hospital based, independent non-hospital based, or home setting.

8.4.C Waiting Time for Kidney Recipients

If a kidney recipient returns to the kidney waiting list, waiting time will be based only on the dates after the most recent kidney transplant, unless the candidate qualifies for reinstatement of waiting time according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.

8.5 Kidney Allocation Classifications and Rankings

8.5.A Candidate Classifications

Each candidate on the kidney waiting list after turning 18 years old receives an Estimated Post Transplant Survival (EPTS) score. A candidate's EPTS score represents the percentage of kidney candidates in the nation with a longer expected post-transplant survival time. EPTS is based on *all* of the following:

1. Candidate time on dialysis
2. Whether or not the candidate has a current diagnosis of diabetes
3. Whether or not the candidate has had any prior solid organ transplant
4. Candidate age

If a kidney recipient returns to the kidney waiting list, only time on dialysis after the most recent kidney transplant applies for number 1 above, candidate time on dialysis, as defined in *Policy 8.4: Waiting Time*.

Each candidate's EPTS score is calculated when the candidate is registered on the waiting list. The OPTN Contractor will update EPTS scores as follows:

- All candidate EPTS scores are updated once each day
- A candidate's EPTS score will be updated anytime the transplant hospital reports changes to any EPTS factor for a candidate

A candidate's raw EPTS score is equal to:

0.047 * MAX(Age - 25, 0) +
-0.015 * Diabetes * MAX(Age - 25, 0) +
0.398 * Prior Solid Organ Transplant +
-0.237 * Diabetes * Prior Solid Organ Transplant +
0.315 * log (Years on Dialysis + 1) +
-0.099 * Diabetes * log(Years on Dialysis + 1) +
0.130 * (Years on Dialysis = 0) +
-0.348 * Diabetes * (Years on Dialysis = 0) +
1.262 * Diabetes

The EPTS calculation uses all the following as binary indicators:

1. Diabetes,
2. Prior solid organ transplant
3. Years on dialysis=0

If a binary indicator is true, then it is replaced by a value of 1.0 in the calculation; otherwise, it is replaced by 0. Fractional calendar years are used for candidate's age and years on dialysis.

The OPTN Contractor's EPTS mapping table is used to convert a candidate's raw EPTS score into an EPTS score. All EPTS scores are rounded to the nearest integer.

The reference population used to determine the top 20% EPTS threshold is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

8.5.B Deceased Donor Classifications

Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The KDPI is the percentage of donors in the reference population that have a KDRI less than or equal to this donor's KDRI.

The donor characteristics used to calculate KDRI are provided in *Table 8-3* below.

Table 8-3: KDRI Factors

This deceased donor characteristic:	Applies to:	KDRI score component:
Age (integer years)	All donors	0.0128*(age-40)
	Donors with age < 18	-0.0194*(age-18)
	Donors with age > 50	0.0107*(age-50)
Ethnicity	African American donors	0.1790
Creatinine (mg/dL)	All donors	0.2200*(creatinine - 1)

This deceased donor characteristic:	Applies to:	KDRI score component:
	Donors with creatinine > 1.5	-0.2090*(creatinine -1.5)
History of Hypertension	Hypertensive donors	0.1260
History of Diabetes	Diabetic donors	0.1300
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0881
Height (cm)	All donors	-0.0464*(height -170) / 10
Weight (kg)	All donors with weight < 80 kg	-0.0199*(weight - 80) / 5
Donor type	DCD donors	0.1330
HCV status	HCV positive donors	0.2400

To calculate KDRI, follow these steps:

1. Sum each of the applicable KDRI score components in *Table 8-3*
2. Apply the antilog (base e) function to this sum
3. Divide the KDRI by the median KDRI value of the most recent donor reference population
4. Determine the KDPI using the OPTN Contractor's KDRI-to-KDPI mapping table

The KDPI score is rounded to the nearest integer.

The KDPI used for allocation is based on the most recent values of donor characteristics reported to the OPTN Contractor before executing a match run.

The reference population used to determine the KDRI-to-KDPI mapping is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

8.5.C Sorting Within Each Classification

Within each classification, candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

8.5.D Allocation of Kidneys by Blood Type

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-4* below:

Table 8-4: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into

Kidneys from Donors with:	Are Allocated to Candidates with:
	candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.
Blood Types A, non-A_1 and AB, non-A_1B	Kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or blood type AB, non-A_1B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

8.5.E Prior Living Organ Donors

A kidney candidate will be classified as a prior living donor if *all* of the following conditions are met:

1. The candidate donated for transplantation, within the United States or its territories, at least *one* of the following:

    - Kidney
    - Liver segment
    - Lung segment
    - Partial pancreas
    - Small bowel segment.

2. The candidate's physician reports *all* of the following information to the OPTN Contractor:

    a. The name of the recipient or intended recipient of the donated organ or organ segment
    b. The recipient's or intended recipient's transplant hospital
    c. The date the donated organ was procured

8.5.F Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in allocation classifications 1 through 10 in allocation sequences according to *Policy 8.5: Kidney Allocation Classifications and Rankings*, the transplant program's HLA laboratory director and the

candidate's transplant physician or surgeon must review and sign a written approval of the unacceptable antigens listed for the candidate. The transplant hospital must document this approval in the candidate's medical record.

8.5.G Prioritization for Liver Recipients on the Kidney Waiting List

If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the same deceased donor, the candidate will be classified as a prior liver recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant date, at least *one* of the following criteria is met:
    - The candidate has a measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
    - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a liver recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a liver and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*

8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-5* below.

Table 8-5: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
2	OPO's DSA	CPRA equal to 100%, blood type identical or permissible	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
4	OPO's region	CPRA equal to 100%, blood type identical or permissible	Any
5	Nation	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Any
6	Nation	CPRA equal to 100%, blood type identical or permissible	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
8	OPO's DSA	CPRA equal to 99%, blood type identical or permissible	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
10	OPO's region	CPRA equal to 99%, blood type identical or permissible	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	Any
12	OPO's DSA	CPRA equal to 98%, blood type identical or permissible	Any
13	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type identical	Any
14	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
19	Nation	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type B	O
23	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	O
25	OPO's region	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
26	Nation	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
27	OPO's region	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	O
28	Nation	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	O
29	OPO's region	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type permissible	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
32	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
35	Nation	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Any
37	Nation	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's DSA	Top 20% EPTS, blood type B	A2 or A2B
43	OPO's DSA	Top 20% EPTS, blood type permissible or identical	Any
44	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, blood type identical	Any
45	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
46	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Any
47	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
48	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
49	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type B	O
50	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	O
51	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	O
52	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
53	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
54	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	Any
55	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Any
56	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Any
57	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
58	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
59	OPO's DSA	EPTS greater than 20%, blood type B	A2 or A2B

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
60	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
61	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
62	OPO's region	Top 20% EPTS, blood type B	A2 or A2B
63	OPO's region	Top 20% EPTS, blood type permissible or identical	Any
64	OPO's region	EPTS greater than 20%, blood type B	A2 or A2B
65	OPO's region	All remaining candidates, blood type permissible or identical	Any
66	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
67	Nation	Top 20% EPTS, blood type B	A2 or A2B
68	Nation	Top 20% EPTS, blood type permissible or identical	Any
69	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-6* below.

Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		no greater than 79%, and blood type identical	
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	Any
43	OPO's DSA	Blood type B	A2 or A2B
44	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
45	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
46	OPO's region	Blood type B	A2 or A2B
47	OPO's region	All remaining candidates, blood type permissible or identical	Any
48	Nation	Registered prior to 18 years old, blood type permissible or identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
49	Nation	Blood type B	A2 or A2B
50	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-7* below.

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, and blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G*: *Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	Any
42	OPO's DSA	Blood type B	A2 or A2B
43	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Blood type B	A2 or A2B
45	OPO's region	All remaining candidates, blood type permissible or identical	Any
46	Nation	Blood type B	A2 or A2B
47	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% will be allocated to adult candidates only.

Kidneys from deceased donors with KDPI scores greater than 85% are allocated to candidates according to *Table 8-8* below.

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type permissible or identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's DSA	0-ABDR mismatch, blood type B	O
19	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
21	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
22	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
23	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
24	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Any
26	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
28	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	Any
29	OPO's region	Blood type B	A2 or A2B
30	OPO's region	All remaining candidates, blood type permissible or identical	Any
31	Nation	Blood type B	A2 or A2B
32	Nation	All remaining candidates, blood type permissible or identical	Any

8.6. Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in *Policy 8.5: Kidney Allocation Classifications and Rankings* before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the deceased donor meets *at least two* of the following criteria:

- Age is greater than 60 years
- Estimated creatinine clearance is less than 65 mL/min based upon serum creatinine at admission
- Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery
- History of longstanding hypertension or diabetes mellitus
- Glomerulosclerosis greater than 15% and less than 50%

The kidneys will be allocated according to sequence of the deceased donor's KDPI.

8.7 Administrative Rules

8.7.A Choice of Right versus Left Donor Kidney

If both kidneys from a deceased donor are able to be transplanted, the transplant hospital that received the offer for the candidate with higher priority on the waiting list will get to choose first which of the two kidneys it will receive.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8* above, or to a combined kidney and non-renal organ candidate, the host OPO determines whether to offer the left or the right kidney.

8.7.B National Kidney Offers

The host OPO must allocate deceased donor kidneys according to *Table 8-9* below.

Table 8-9: National Kidney Offers

A national 0-ABDR mismatch candidate	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
A national 100% CPRA candidate in match classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8*	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
Any other national candidates	Contact the Organ Center for assistance allocating the kidney

8.7.C Multi-Organ Combinations Allocated but Not Transplanted

If a multi-organ combination that includes a kidney is allocated but the kidney transplant is not performed, the kidney must be reallocated according to *Policy 5.9: Released Organs*.

History

Policy 3.5: Allocation of Deceased Kidneys: 9/17/2007; 12/18/2007; 6/20/2008; 6/22/2010; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012
Policy 8: Allocation of Kidneys: 11/12/2013 (2/1/2014); 3/7/14; 9/15/2014 (10/30/14); 6/24/2013 (12/4/2014); 11/12/2014 (5/1/2015); 6/2/2015 (9/1/2015); 6/6/2016 (9/1/2016); *Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or Equal to 20%* and *8.7.A: Mandatory Sharing:* 6/6/2016 (6/29/2017); *Policies 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%*, *8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%*, *8.5.J: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35%*, and *8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%*: 6/6/2016 (8/10/2017); *Policy 8.5.G Prioritization for Liver Recipients on the Kidney Waiting List*: 4/24/2017 (8/10/2017)

Pending Implementation

Policies 8.5: Kidney Allocation Classifications and Rankings and *8.6: Double Kidney Allocation*: 12/4/2017 (TBD) and 12/4/2017 (TBD)

Notes

- For membership and personnel requirements for kidney programs, see the *OPTN Bylaws, Appendix E*.

- For information on reporting candidate's unacceptable antigens to the OPTN Contractor, see *Policy 5.3.A: Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA).*
- For requirements to have a candidate's waiting time reinstated for immediate and permanent non function of a transplanted kidney, see *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.
- For allocation of multi-organs that include a kidney, see *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets*.

EXHIBIT D

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

George Sigounas, MS, PhD
Administrator

Attachment

EXHIBIT E

UNOS
UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

700 North 4th Street, Richmond, VA 23219
tel: 804-782-4800
fax: 804-782-4816
www.unos.org

Brian M. Shepard
Executive Director & CEO

TO: George Sigounas, MS, Ph.D.
Administrator
Health Resources and Services Administration
Department of Health and Human Services

FROM: Sue Dunn
President, OPTN/UNOS Board of Directors

Brian Shepard
OPTN Executive Director
CEO, United Network for Organ Sharing

DATE: August 13, 2018

RE: Plan for Amending Organ Allocation Policies

Your letter dated July 31, 2018 contained the following direction to the OPTN:

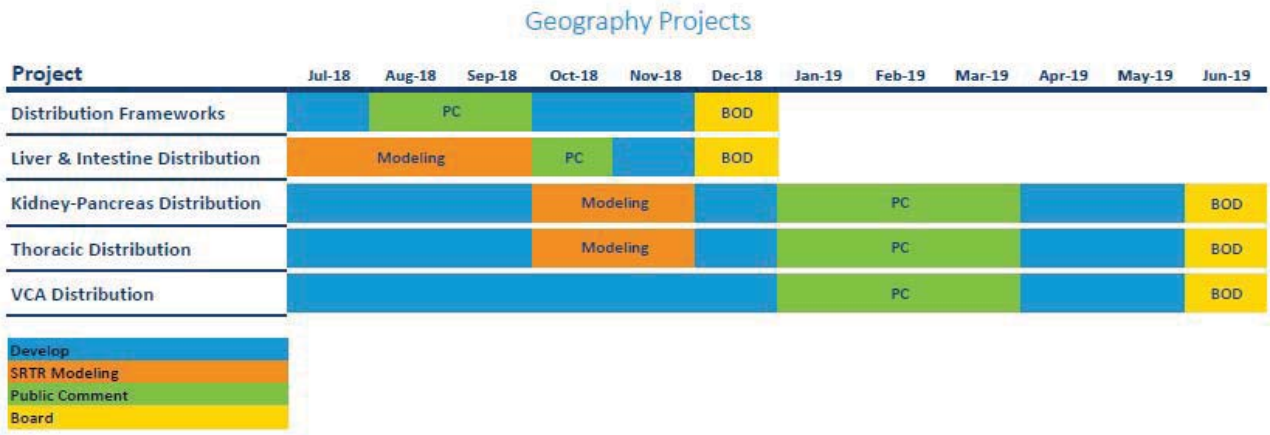
> *submit a detailed report by August 13, 2018, for review by HRSA outlining the OPTN's plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies, for ensuring that such policies satisfy the requirements of the OPTN final rule (including the OPTN's plans for ensuring that the OPTN Board provides an appropriate rationale), and steps and timelines that will be followed.*

The following responds to this request.

Executive Summary

Work to eliminate DSAs and regions from organ allocation policies is already underway. The Policy Oversight Committee (POC) and Executive Committee reviewed and approved new project plans to remove DSAs and regions from all of the organ-specific allocation policies by June 2019. New tools and processes are being implemented to ensure that the revised policies are consistent with the final rule and that the OPTN Board identifies the rationale supporting compliance with these requirements.

The chart below summarizes the timeframe for completing this work.



Approaches

We have divided this work into five related projects: liver and intestine; kidney and pancreas; heart and lung; vascular composite allografts (VCA); and other policies. These organ combinations were selected because they currently have overlapping allocation policies. Maintaining these organ combinations will allow changes to be developed and implemented in a timely and informed manner. Additionally, changes to general allocation policies that refer to DSA and regional boundaries will be developed concurrently with the above policy projects.

Staff from the policy, research, IT, and other departments will continue to provide analysis and recommendations to the sponsoring committees for these projects. We have already discussed these timelines with the SRTR in order to confirm that they are able to provide the necessary modeling to meet this timeline. We will expedite the decision-making process by using a modified version of our typical policy development process that maintains the key components of data review, public comment, and Board approval.

HRSA will continue to receive meeting materials for and invitations to participate in all committee meetings. HRSA will also receive regular updates through conversations with HRSA's OPTN Contracting Officer's Representative. UNOS will continue to be available to answer questions from HRSA. UNOS staff continues to update the donation and transplantation community regarding allocation changes through committee and regional meetings, as well as community email updates and the OPTN website.

Compliance with the Final Rule

The OPTN Board of Directors will ensure that allocation policies are based upon the requirements of NOTA and the OPTN Final Rule, using a combination of tools and processes to direct the committees' work and document supporting rationale for policy decisions:

- Tools:
    - Meeting materials will structure committee decisions in the context of the requirements of the OPTN Final Rule. This includes presentations used during committee discussions and any reference materials sent in advance of the meetings.
- Processes:
    - OPTN Committee Data Analysis Requests and SRTR Simulation Requests will contain an explanation of how the request is related to the requirements of the OPTN Final Rule.
    - Analysis of proposed policy revision impacting geographic distribution will be conducted utilizing the recently approved Geographic Principles of Organ Distribution and the requirements of the Final Rule.
- Documentation:
    - Meeting summaries, public comment proposals, and board briefing papers will synthesize committee discussions and decisions to clearly identify the basis for and rationale supporting policy revisions in the context of the requirements of the OPTN Final Rule. The rationale for geographic boundaries in allocation will include supportive data describing the need for the boundaries and linking the decision to the requirements of the Final Rule.

Organ-Specific Tasks and Timelines

Below are the major tasks and timelines for the various committee projects.

Liver and Intestine

3rd Quarter 2018: The Liver-Intestine Committee's first task was to submit their modeling request to the SRTR. This was completed in July 2018 for a model distribution system that uses distance-based circles for liver distribution. Subsequently, the committee's focus turned to the transition plan for the National Liver Review Board (NLRB). The NLRB policy approved by the Board in December 2017 ties the exception scores to the Median MELD at Transplant (MMaT) to the DSA of the candidate. The Committee is developing a new method to calculate the MMaT that is not restricted by DSA or region. The Committee will consider changes to simultaneous liver-kidney allocation and liver-intestine allocation. The Committee will also discuss changes to any liver variances that restrict organ allocation by DSA or region.[1] The Committee expects to receive the results of SRTR modeling requests in late September 2018, at which time they will then analyze the options for compliance with the Final Rule and determine which model will be released for public comment. The POC and Executive Committee will review the Committee's rationale and evidence supporting the proposed model and approve the

[1] Some variances use DSA or region for administrative purposes. For example, Policy 9.9.A, *Open Variance for Segmental Liver Transplantation*, contains a requirement for each DSA or region to discuss the results of the variance. This is administratively efficient and does not restrict access to organs. We do not intend to change these variances.

proposal for revisions to the liver-intestine policy before it is released for public comment.

4th quarter 2018: Public comment is scheduled to begin in early October. Prior to public comment, the POC and Executive Committee will review the proposal to ensure there is a rational basis with regard to geographic restriction supporting compliance with the OPTN Final Rule. During this period, we will host webinars to collect feedback from the community. This will include targeted outreach to stakeholders such as the American Association of the Study of Liver Diseases (AASLD).

The Committee will convene on November 2 for an in-person meeting. At this meeting, the Committee will review the results of public comment and recommend a policy proposal to the Board of Directors. The Board will meet in December to review and confirm the rationale for the proposed revisions in the context of the Final Rule requirement and approve changes to the liver allocation policies. In anticipation of this vote, UNOS staff will begin preparations to implement the amended policies, including IT programming and education for members.

1st quarter, 2019: Following the December 2018 Board of Directors meeting, UNOS staff will implement the amended policies, including community education in a variety of formats.

Kidney and Pancreas

3rd quarter 2018: A working group of the Kidney and Pancreas Transplantation Committees has been formed. The Kidney Committee will sponsor a proposal to amend kidney and pancreas policies with input from the Pancreas Committee. The Committee's Q3 focus will be to develop a modeling request for the SRTR which will include discussions of the rationale and evidence for restricting distribution including for example the distance at which transportation methods change from driving to flying as a justification for restriction based on efficient management of the system. Additionally, the Committee will discuss the different cold ischemia time (CIT) limits of kidneys vs. pancreas and kidneys of various KDPI scores as a relevant consideration in distribution policy to avoid organ wastage. The Committee will also discuss which elements of distribution need to be consistent for all kidneys and between kidneys and pancreata.

4th quarter 2018: The Committee will discuss any changes necessary for other kidney or pancreas policies and guidance document that currently utilize DSAs or regions. Both the Kidney and Pancreas Transplantation Committees are scheduled to hold in-person Committee meetings in Q4. The Committees expect to receive the results of the SRTR modeling request in Q4. Also during this time, the Committee will evaluate the models for compliance with the Final Rule and adapt their proposal in response to that analysis as well as any lessons learned from the Liver Committee's public comment proposal and subsequent Board discussions. The Kidney Committee will advance a proposal for spring 2019 public comment.

1st quarter 2019: Public comment is scheduled from January to March, 2019. The Committee will educate the community about the proposal and receive feedback during public comment. This will include targeted outreach to stakeholders such as National Kidney Foundation (NKF), the American Society of Nephrology (ASN), and International Pancreas & Islet Transplant Association (IPITA).

2nd quarter 2019: The Kidney and Pancreas Committees will review the results of public comment and recommend a policy proposal to the Board of Directors. The Board of Directors will meet in June 2019 and review and confirm the rationale for the proposed revisions in the context of the Final Rule requirement and approve changes to the kidney and pancreas allocation policies. In anticipation of this vote, UNOS staff will begin preparations to implement the amended policies. This will include planning for IT programming and education for members.

3rd and 4th quarter 2019: Because current kidney policy uses DSA and regional boundaries more extensively than other organs, designing a new policy while avoiding unintended consequences may take a second round of revisions after the first public comment cycle. If the Committees believe a second round of public comment is necessary, they will report their progress and reason for utilizing a second round of public comment to the Board of Directors in June, and then offer a revised proposal for public comment in August 2019 and a policy proposal to the Board for approval in December 2019.

Heart and Lung

3rd quarter 2018: The Thoracic Committee will sponsor a proposal for changes to thoracic organ allocation. Lung allocation does not currently contain references to DSA or region; however, heart allocation policies do utilize DSAs and therefore must be amended. The Committee will consider whether lung and heart must use identical distribution models. In either situation, the Committee will discuss the rationale and evidence consistent with the Final Rule for selecting a replacement for DSA in heart allocation. Additionally, the Committee will discuss whether a 250 nautical mile circle for initial lung distribution should be further revised given data collected since the new policy went into effect and within the context of the Final Rule requirements. During Q3, the Committee will submit a new modeling request to the SRTR.

4th quarter 2018: The Thoracic Committee will discuss any changes necessary for other thoracic policies and guidance documents that currently utilize DSAs or regions. These include heart-lung allocation, sensitized patients, and review board guidelines. The Committee expects to receive the results of the SRTR modeling in Q4. The Committee will evaluate any proposed revisions for compliance with the Final Rule and also adapt their proposal in response to any lessons learned from the Liver Committee's public comment proposal and subsequent Board discussions. The Thoracic Committee will vote on the policy proposal for spring 2019 public comment.

1st quarter 2019: Public comment is scheduled from January to March, 2019. The Committee will educate the community about the proposal and receive feedback during public comment. This will include targeted outreach to stakeholders such as The International Society for Heart & Lung Transplantation (ISHLT).

2nd quarter 2019: The Committee will review the results of public comment and recommend a policy proposal to the Board of Directors. The Board of Directors will meet in June 2019 to review and confirm the rationale for the proposed revisions in the context of the Final Rule requirement and approve changes to the thoracic allocation policies. In anticipation of this vote, UNOS staff will begin preparations to implement the amended policies. This will include planning for IT programming and education for members.

VCA

3rd quarter 2018: The SRTR does not currently provide modeling for VCA, and the number of candidates and transplants are far fewer than for other organs. The VCA committee will discuss considerations including transportation efficiency, organ viability (such as differing CIT limits of various types of VCAs) and other factors that support restricting distribution consistent with the Final Rule The Committee will rely, in part, upon published research from orthopedic and reconstructive surgery fields. Finally, the Committee will discuss which elements of distribution need to be consistent for all types of VCA.

4th quarter 2018: The Committee is scheduled to hold an in-person meeting in October. At this meeting, the Committee will formulate a proposed revision to current distribution policy, review and confirm the rationale for the proposed revisions in the context of the Final Rule requirement and offer the proposed revision for spring 2019 public comment.

1st quarter 2019: Public comment is scheduled for January to March, 2019. The Committee will educate the community about the proposal and receive feedback during public comment during Q1. This will include targeted outreach to stakeholders such as American Society of Reconstructive Transplantation (ASRT).

2nd quarter 2019 The VCA Committee will review the results of public comment and recommend a policy proposal to the Board of Directors. The Board of Directors will meet in June 2019 to review and confirm the rationale for the proposed revisions in the context of the Final Rule requirement and approve changes to the VCA allocation policies. In anticipation of this vote, UNOS staff will begin preparations to implement the amended policies. This will include planning for IT programming and education for members.

Moving towards one distribution framework

3rd quarter 2018: The Ad Hoc Committee on Geography has offered three distribution frameworks for public comment from now until October 3. The goal of this work is to receive stakeholder feedback on three identified distribution frameworks, all three of which can be customized to accommodate organ-specific criteria in a manner that complies with the Final Rule. The Committee will also educate the community about the Board's June 2018 adoption of Geographic Principles for Organ Distribution, a tool to help committees and the community understand the geographic requirements of the Final Rule.

4th quarter 2018: The Ad Hoc Geography Committee will meet monthly to receive updates on the proposals and provide guidance for the sponsoring committees to ensure policy revisions are evidence-based and compliant with the Final Rule. The Committee will review the results of public comment and depending on the feedback, may identify a single distribution framework to recommend to the Board of Directors. The Board of Directors will meet in December 2018 to review this recommendation and potentially select a single distribution framework for all organ types over time.

1st quarter 2019: The Geography Committee will meet monthly to receive updates on the proposals and provide guidance for the sponsoring committees regarding any restriction of organ distribution and evaluation of alignment with the Final Rule.

Conclusion

After these policy revisions are implemented, the OPTN will continue to monitor the results of new policies, analyze data, and make timely revisions. The goal of the OPTN is to ensure the work, responsive to your letter, is conducted in a time-frame that is as expeditious as possible while ensuring appropriate process and analysis to avoid unintended harm to waiting patients and to confirm compliance with the Final Rule.

EXHIBIT F

OPTN Committee Data Analysis Request Form

DHHS Contract #234-2005-370011C
Task 1.s., Item 23

Date Form Submitted to HRSA: **July 19, 2018**

Requesting Committee: **Liver and Intestinal Organ Transplantation Committee**

Date Committee Met: **July 10, 2018**

Date of Next Meeting: **July 19, 2018**

OPTN staff member referring Committee's requests: **Samantha M. Noreen, Ph.D.**

Chair Approval? **Yes**

ANALYSES REQUESTED:

• Descriptive Statistical Requests (responsibility of OPTN contractor)

- None

• Inferential Statistical Requests (responsibility of SRTR contractor)

Data Request 1: Provide LSAM data on revised proposals for liver redistribution

Background: On June 25, 2018 the OPTN Board of Directors directed the Liver and Intestinal Organ Transplantation Committee ("the Committee") to propose changes to policy removing any reference to DSA and Region as units of allocation in response to a critical comment submitted to the Secretary of Health and Human Services on May 30, 2018. The OPTN has committed to a multi-step plan to eliminate the use of DSAs in liver distribution in a deliberative manner and within a timeframe that will reduce the likelihood of unintended consequences.

Towards the goal of utmost compliance with the Final Rule, the Committee has discussed options for a revised allocation proposal that will reduce disparities in access to liver transplants, as well as decrease potential unintended consequences of an expedited policy change. The OPTN Final Rule requires that organ allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required by" the OPTN Final Rule. (42 CFR 121.8(a)(8).) Furthermore, the OPTN Final Rule states that "Allocation policies shall be designed to achieve equitable allocation of organs among patients … [by] (3) Distributing 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).) Consistent with these requirements, the Committee has discussed limitations on the feasibility of national organ distribution. Committee members have stated that there are improved outcomes for livers with lower cold ischemic time (CIT). CIT increases as the distance between the donor hospital and transplant hospital increase. This relationship and the desire to decrease CIT justifies a local priority due to the need to "achieve the best use of donated organs." (42 CFR 121.8(a)(2).) Furthermore, committee members have noted that liver surgeons often times travel to participate in organ procurement efforts. Therefore, organ offers that require additional travel time result in more surgeons away from the hospital and unavailable to perform transplants. This justifies a local priority due to the need "to promote the efficient management of organ placement." (42 CFR 121.8(a)(5).)

The two agreed-upon options to consider moving forward are outlined below, as Allocation Framework 1 and Allocation Framework 2. The goal of modeling both allocation frameworks is to compare these two proposals and inform the choice of the final policy proposal for a special public comment period, to begin October 8, 2018, prior to the December 2018 Board of Directors meeting.

The request laid out below will aid the Committee in their recommendation to the Board of Directors regarding the most appropriate policy that should be adopted.

Strategic Goal or Committee Project Addressed: Evaluate outcomes associated with the removal of DSA and Region as units of allocation. The project is in alignment with the strategic goal to improve equity in access to transplants.

Request: Using the most recently available LSAM version and data, model the distribution systems outlined below as **Allocation Framework 1** and **Allocation Framework 2**.

Allocation Framework 1: Acuity Circles

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[**500/600**]nm	Adult or pediatric status 1A
2	[**500/600**]nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 37
4	[**250/300**]nm	MELD or PELD of at least 37
5	[**500/600**]nm	MELD or PELD of at least 37
6	150nm	MELD or PELD of at least 33
7	[**250/300**]nm	MELD or PELD of at least 33
8	[**500/600**]nm	MELD or PELD of at least 33
9	150nm	MELD or PELD of at least 29
10	[**250/300**]nm	MELD or PELD of at least 29
11	[**500/600**]nm	MELD or PELD of at least 29
12	150nm	MELD or PELD of at least 15
13	[**250/300**]nm	MELD or PELD of at least 15
14	[**500/600**]nm	MELD or PELD of at least 15
15	National	Adult or Pediatric Status 1A
16	National	Pediatric Status 1B
17	National	MELD or PELD of at least 15
18	150nm	MELD or PELD less than 15
19	**[250/300]nm**	MELD or PELD less than 15
20	[**500/600**]nm	MELD or PELD less than 15
21	National	MELD or PELD less than 15

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Pediatric status 1A
2	[500/600]nm	Adult status 1A
3	[500/600]nm	Pediatric status 1B
4	[500/600]nm	Any PELD
5	[500/600]nm	Any MELD and 12 to 17 years old
6	Nation	Pediatric status 1A
7	Nation	Adult status 1A
8	Nation	Pediatric status 1B
9	Nation	Any PELD
10	Nation	Any MELD and 12 to 17 years old
11	[500/600]nm	Any MELD and at least 18 years old
12	Nation	Any MELD and at least 18 years old

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Pediatric status 1A
2	Nation	Pediatric status 1A and 0 to 11 years old
3	[500/600]nm	Adult status 1A
4	[500/600]nm	Pediatric status 1B
5	[500/600]nm	Any PELD
6	[500/600]nm	Any MELD and 12 to 17 years old
7	Nation	Pediatric status 1A and 12 to 17 years old
8	Nation	Adult status 1A
9	Nation	Pediatric status 1B and 0 to 17 years old
10	Nation	Any PELD
11	Nation	Any MELD and 12 to 17 years old
12	[500/600]nm	Any MELD and at least 18 years old
13	Nation	Any MELD and at least 18 years old

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Livers from DCD donors or donors at least 70 years old are allocated to candidates according to the table below:

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[**500/600**]nm	Adult or Pediatric status 1A
2	[**500/600**]nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 15
4	[**250/300**]nm	MELD or PELD of at least 15
5	[**500/600**]nm	MELD or PELD of at least 15
6	Nation	Adult or Pediatric status 1A
7	Nation	Pediatric status 1B
8	Nation	MELD or PELD of at least 15
9	150nm	MELD or PELD less than 15
10	[**250/300**]nm	MELD or PELD less than 15
11	[**500/600**]nm	MELD or PELD less than 15
12	Nation	MELD or PELD less than 15

- **Simulation 1A** will use the distances 150nm, **250nm**, and **500nm**, respectively. Exception scores assigned following previously modeled redistribution proposals (current implemented policy).
- **Simulation 1B** will use the distances 150nm, **300nm**, and **600nm**, respectively. Exception scores assigned following previously modeled redistribution proposals (current implemented policy).

Allocation Framework 2: Broader 2-Circle Distribution

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Adult or pediatric status 1A
2	500nm	Pediatric status 1B
3	250nm	MELD or PELD of at least **[35/32]**
4	150nm	MELD or PELD of at least 15
5	250nm	MELD or PELD of at least 15
6	500nm	MELD or PELD of at least 15
7	National	Adult or Pediatric Status 1A
8	National	Pediatric Status 1B
9	National	MELD or PELD of at least 15
10	150nm	MELD or PELD less than 15
11	250nm	MELD or PELD less than 15
12	500nm	MELD or PELD less than 15
13	National	MELD or PELD less than 15

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Pediatric status 1A
2	500nm	Adult status 1A
3	500nm	Pediatric status 1B
4	500nm	Any PELD
5	500nm	Any MELD and 12 to 17 years old
6	Nation	Pediatric status 1A
7	Nation	Adult status 1A
8	Nation	Pediatric status 1B
9	Nation	Any PELD
10	Nation	Any MELD and 12 to 17 years old
11	500nm	Any MELD and at least 18 years old
12	Nation	Any MELD and at least 18 years old

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Pediatric status 1A
2	Nation	Pediatric status 1A and 0 to 11 years old
3	500nm	Adult status 1A
4	500nm	Pediatric status 1B
5	500nm	Any PELD
6	500nm	Any MELD and 12 to 17 years old
7	Nation	Pediatric status 1A and 12 to 17 years old
8	Nation	Adult status 1A
9	Nation	Pediatric status 1B and 0 to 17 years old
10	Nation	Any PELD
11	Nation	Any MELD and 12 to 17 years old
12	500nm	Any MELD and at least 18 years old
13	Nation	Any MELD and at least 18 years old

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Livers from DCD donors or donors at least 70 years old are allocated to candidates according to the table below:

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Adult or Pediatric status 1A
2	500nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 15
4	500nm	MELD or PELD of at least 15
5	Nation	Adult or Pediatric status 1A
6	Nation	Pediatric status 1B
7	Nation	MELD or PELD of at least 15
8	150nm	MELD or PELD less than 15
9	500nm	MELD or PELD less than 15
10	Nation	MELD or PELD less than 15

- **Simulation 2A** will use the MELD/PELD score thresholds of **35**, such that the sharing threshold is a MELD or PELD score of at least 35 ("Share 35"). Exception scores assigned following previously modeled redistribution proposals (current implemented policy).
- **Simulation 2B** will use the MELD/PELD score thresholds of **32**, such that the sharing threshold is a MELD or PELD score of at least 32 ("Share 32"). Exception scores assigned following previously modeled redistribution proposals (current implemented policy).

Based on the above frameworks, provide the following metrics. Relevant metrics will be stratified by all candidates, non-exception candidates, HCC candidates, and other exceptions. Metrics to be assessed for the overall population (nationwide) include:

1. Median MELD/PELD score at transplant (MMaT)**
2. Variance in the median MELD/PELD score at transplant**
3. Counts of transplants**
4. Transplant rates**
5. Variance in transplant rates
6. Counts of waiting list deaths**
7. Waitlist mortality rates**
8. Variance in waiting list mortality rates
9. Post-transplant patient survival**
10. Median transport distance**
11. Median transport time**
12. Percent of organs flown for transport**

** *These metrics can be prioritized for initial results for **both** allocation frameworks, others can be provided in a following report if necessary.*

Relevant metrics will be displayed in maps by DSA and tables provided in an appendix for DSA level results for:

- Median MELD/PELD score at transplant
- Counts of transplants
- Transplant rates
- Counts of waiting list deaths
- Waiting list mortality rates
- Percent of organs flown for transplant (recovered in DSA, flown out)
- Percent of organs flown for transplant (transplanted in DSA, flown in)

Items 1 – 9 should also be assessed by the following subgroup populations:

- OPTN Region: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11^^
- Age: pediatric (under 18 at listing) and adult (18+ at listing)^^
- Sex: female and male^^
- Race/ethnicity: African American, Asian/Pacific Islander, Caucasian, Hispanic^^
- MELD/PELD group: < 15, 15-24, 25-28, 29-31, 32-34, 35+ (includes Status 1s)^^
- Exception status: No exceptions, HCC exception, Other exception^^
- Urbanicity: urban vs rural, based on RUCA codes (Individually, and grouped by metropolitan vs micropolitan + small town + rural)
- Insurance status: public and private
- Cumulative Community Risk Score (CCRS) grouped in units of 10 (0-10, 11-20, 21-30, 31-40)

Items 10 – 12 should also be assessed by the following subgroup populations:

- OPTN Region: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11^^
- MELD/PELD group: < 15, 15-24, 25-28, 29-31, 32-34, 35+ (includes Status 1s)^^

^^ *These subgroup populations can be prioritized for initial results for **both** allocation frameworks, others can be provided in a following report if necessary.*

EXHIBIT G

OPTN | UNOS

Public Comment Proposal

Frameworks for Organ Distribution

OPTN/UNOS Ad Hoc Geography Committee

Prepared by: Matthew A. Prentice, MPH
UNOS

Contents

Frameworks for Organ Distribution

Affected Policies: *N/A*
Sponsoring Committee: *Ad Hoc Geography Committee*
Public Comment Period: *August 3, 2018 – October 3, 2018*

Executive Summary

The Ad Hoc Geography Committee was formed in December 2017 to examine the geographic distribution of organs. The Committee was charged with:

- Establishing defined guiding principles for the use of geographic constraints in organ allocation
- Reviewing and recommending models for incorporating geographic principles into allocation policies
- Identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

The OPTN Final Rule sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency.[1] The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of the Rule.

On June 11, 2018, the OPTN/UNOS Board of Directors adopted principles to guide future organ transplant policy relating to geographic aspects of organ distribution. Additionally, the Board of Directors accepted the Ad Hoc Geography Committee's recommendation to request community feedback on the recommended distribution frameworks, with a goal of identifying a single, preferred distribution framework to be used across organs. This proposal includes three distribution frameworks identified by the Ad Hoc Geography Committee as being in alignment with the adopted principles of geographic distribution and the OPTN Final Rule.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

Yes, the Ad Hoc Geography Committee (hereafter, "the Committee") requests feedback from the community regarding the three distribution frameworks. The goal is to identify a single framework to be used across organs. The community is encouraged to provide their rationale for preferring one specific framework of the three proposed.

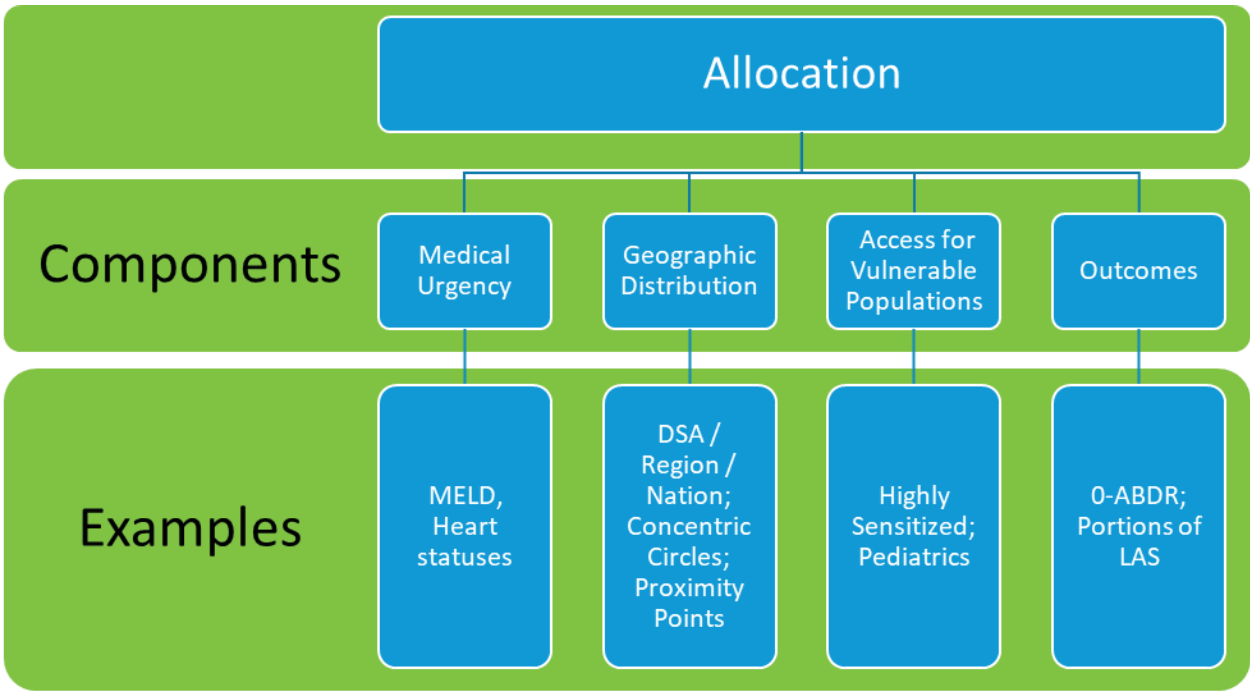
Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required by the distribution frameworks. This information assists the Board in considering the proposal and its impact on the community.

[1] 42 C.F.R. §121.8(a)

What problem will this proposal address?

Geographic distribution is one of several components in OPTN allocation policies. Allocation is a combination of multiple factors, including medical urgency, geographic location, access for vulnerable populations, and outcomes. The Committee's charge was to focus only on the frameworks used by the OPTN to determine geographic distribution. **Figure 1** shows the role of geographic distribution among other factors in organ allocation.

Figure 1: The role of geographic distribution among other factors in organ allocation



Historically, organ allocation policies have been developed and proposed by individual OPTN Committees. This approach has resulted in different distribution frameworks used in the respective organ-specific policies. **Figure 2** shows the current distribution frameworks with respect to each organ.

Figure 2: Current organ distribution frameworks, including board-approved and pending implementation

Organ-Specific Allocation	Distribution Framework
Kidney	Region, DSA, and National
Pancreas, Kidney-Pancreas, and Islets	Region, DSA, and National
Liver and Liver-Intestine	Region + Circle, DSA, and National
Intestine	Region, DSA, National
Lung	Zone
Hearts	Zone and Zone + DSA
Vascular Composite Allografts	Region and National

The DSA (Donation Service Area) is "the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals."[2] As shown in Figure 2, allocation policies for kidneys, livers, intestines, and pancreas incorporate the DSA as a unit of distribution. Similarly, those organ types, along with vascular composite allografts, use OPTN regions as another unit of distribution in allocation policy.[3] Zones are concentric bands that are centered around the donor hospital used for the distribution of thoracic organs.[4]

The Committee identified two prominent issues with the current variation in distribution frameworks among organs, including:

1. Variation in compliance with requirements in the OPTN Final Rule
2. Inefficiencies in programming changes to OPTN allocation policy

1. Variation in compliance with requirements in the OPTN Final Rule

The OPTN Final Rule requires that allocation policies "not be based on the candidate's place of residence or place of listing" except as required by permissible reasons in the Final Rule.[5] These permissible reasons include achieving the best use of organs, avoiding organ wastage, promoting patient access, and promoting the efficient management of organ placement.[6] In the context of the current methods for organ distribution, the different organ systems use different geographic units to achieve these goals. (Ex. a geographic unit nearby the donor hospital can decrease the amount of flying required for organ recovery and thus promotes the efficient management of organ placement.)

The organ systems use different methods for balancing the regulatory requirements and have achieved varying levels of balance amongst those requirements. The Committee acknowledges that from an overall network perspective, there is very little rationale for thoracic organs to be distributed based on a candidate's distance from the donor hospital, while all other organs are based on the candidate's location

[2] OPTN/UNOS *Policy 1: Definitions*, "Donation Service Area (DSA)." https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. Accessed on July 11, 2018.
[3] OPTN/UNOS *Policy 1: Definitions*, "Region." https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. Accessed on July 11, 2018.
[4] OPTN/UNOS *Policy 1: Definitions*, "Zone." https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. Accessed on July 11, 2018.
[5] 42 C.F.R. §121.8(a)(8).
[6] 42 C.F.R. §121.8(a).

within an OPTN Region and DSA. The liver allocation policy adopted by the Board in December 2017 uses an out-of-region proximity circle to expand distribution. This does not exist in the other policies that utilize OPTN Region and DSAs.[7] If there is an inherent benefit of one approach over the other, then that approach should be consistent among all organ groups.

2. Inefficiencies in programming changes to OPTN allocation policy

The OPTN currently maintains programming architecture for all organ allocation. Within each organ-specific allocation, there is complexity based on candidate age, donor characteristics, blood type compatibility, and other factors. The Committee foresees a future programming architecture where a singular distribution framework will increase the efficiency in which the OPTN can program new allocation changes. This will further enhance the OPTN's ability to respond to the ever-changing field of transplantation by developing policy and implementing solutions efficiently.

The Committee acknowledges that clinical and logistical specificity by organ type is critical to organ allocation.[8] There will always be organ-specific parameters in allocation policy. However, a singular framework will allow future policy changes to be uniformly compliant with the OPTN Final Rule and enhance the efficiency of the OPTN in responding to changes in transplantation through a more uniform and efficient approach to developing and implementing policy changes.

Why should you support this proposal?

The goal of this proposal is to receive feedback and build consensus around a singular framework of organ distribution. The consensus built around a singular framework will allow the OPTN and organ specific committees to begin moving towards a framework that ensures compliance with federal law and increases the ability for the OPTN to respond to innovations in the field of transplantation in an efficient and uniform manner across organs.

How was this proposal developed?

The Committee was formed in December 2017 and charged with:

- Establishing defined guiding principles for the use of geographic constraints in organ allocation
- Reviewing and recommending models for incorporating geographic principles into allocation policies
- Identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

The OPTN/UNOS Board of Directors approved the following Principles of Geographic Distribution on June 12, 2018:

> Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.
>
> Geographic distribution may be constrained in order to:
>
> 1. Reduce inherent differences in the ratio of donor supply and demand across the country
> 2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
> 3. Increase organ utilization and prevent organ wastage

[7] *Redesigning Liver Distribution*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf (accessed July 5, 2018).
[8] Additionally, the OPTN Final Rule requires that "organ allocation policies … shall be specific for each organ type." 42 C.F.R. §121.8(a)(4).

4. Increase efficiencies of donation and transplant system resources[9]

During the development of these principles, the Committee began to analyze frameworks for organ distribution. This effort involved a review of current OPTN policies, previous distribution frameworks developed by researchers in the community, and novel concepts put forth by members of the community and Scientific Registry of Transplant Recipients (SRTR).

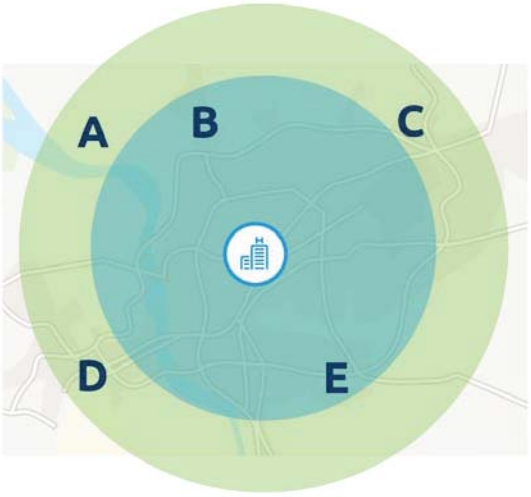
The Committee used a survey to begin to focus on distribution frameworks that are in line with the OPTN Final Rule and the principles developed by the Committee. The Committee identified three frameworks for geographic distribution that are consistent with the principles and the Final Rule. The Committee recommends further discussion by the Board and by the community on the merits of the three frameworks, but agrees that the OPTN would be best served by adopting a single common framework to be applied to all organ allocation policies. Even within a common framework, each organ would have medically determined factors that apply specifically to that organ. The three frameworks identified by the Committee are:

1. Fixed Distance from the Donor Hospital
2. Mathematically Optimized Boundaries
3. Continuous Distribution

1. Organ Distribution Based on Fixed Distance from the Donor Hospital

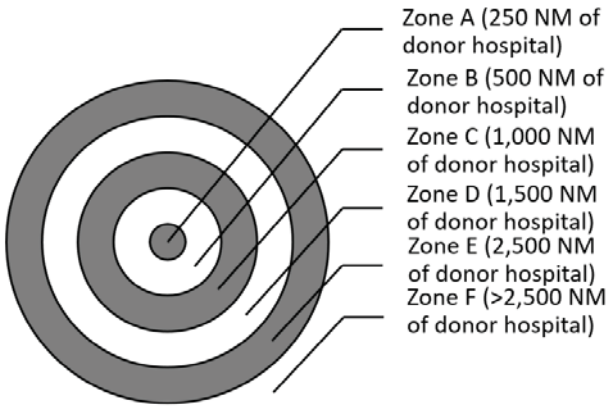
This framework utilizes a system of fixed geographic units based on the distance from the donor hospital to the candidate's place of listing. One example of this framework is currently utilized in heart and lung distribution and referred to as concentric circles or zones. The changes to liver distribution approved by the Board of Directors in December 2017 partially utilizes a similar concept to add a proximity circle around a donor hospital, however the changes to liver distribution still maintain the regional boundaries and the proximity circle expands the geographic unit of allocation outside of the region.

Figure 3: Representation of Organ Distribution Based on Fixed Distance from the Donor Hospital



[9] *Geographic Organ Distribution Principles and Models Recommendations Report*, OPTN/UNOS Geography Committee, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed July 5, 2018).

Figure 4: Current Lung Distribution Policy, concentric circles in nautical miles (NM) around the donor hospital



The Committee discussed several advantages of this distribution model and its alignment with the principles. Distance from a donor hospital is related to multiple interests recognized by the OPTN Final Rule: organ outcomes, system efficiency, and patient access. Committee members have stated that there are improved outcomes for organs with lower cold ischemic time (CIT). CIT increases as the distance between the donor hospital and transplant hospital increase. A fixed distance circle could decrease CIT and justify some local priority due to the need to "achieve the best use of donated organs."[10]

Furthermore, committee members noted that some transplant surgeons travel to participate in organ procurement efforts. Therefore, organ offers that require additional travel time result in more surgeons away from the hospital and unavailable to perform transplants.

Additionally, organ recoveries that require air travel increase the financial cost of organ placement. A fixed distance circle placed at the point where procurement typically changes from driving to flying could limit the travel time or number of organs flying. This distance could be organ specific (ex. hearts could travel by air at shorter distances due to the impact of CIT). Similarly, this distance could depend upon donor characteristics if they impact transplant outcomes (ex. DCD organs). This increase in cost could justify some local priority due to the need "to promote the efficient management of organ placement."[11]

The size constraints of the circle can also reduce inherent differences in potential donor supply and demand by broadening distribution across multiple DSAs and current regional boundaries. This would be consistent with the Final Rule charge that "allocation policies … (5) shall be designed to … promote patient access."[12] However, a fixed distance circle drawn too small could improperly prioritize local organ offers and fail to balance all of the requirements in the OPTN Final Rule.

Additionally, the use of fixed distance circles can minimize travel of organs for patients with similar allocation priority by ordering candidates within a zone by organ-specific measures of medical urgency. For example, lung distribution candidates are ordered within a zone by their lung allocation score (LAS). Similar stratification can be achieved in other organs by their medical urgency score (MELD score for liver distribution) or by waiting time.

A disadvantage of this distribution model is the inherent "cliffs" between each concentric circle. For example, within a policy that employs 500 mile circles, a candidate with an LAS of 50 at a transplant program 499 miles away from the donor hospital and another candidate with an LAS of 50 501 miles away from the donor hospital are treated differently, although in terms medical urgency they are identical and in terms of geographic proximity they are very similar. Those differences are smaller in circle models that assign some number of proximity points to each circle than in circle models that offer to all candidates within one circle before offering to the subsequent circle.

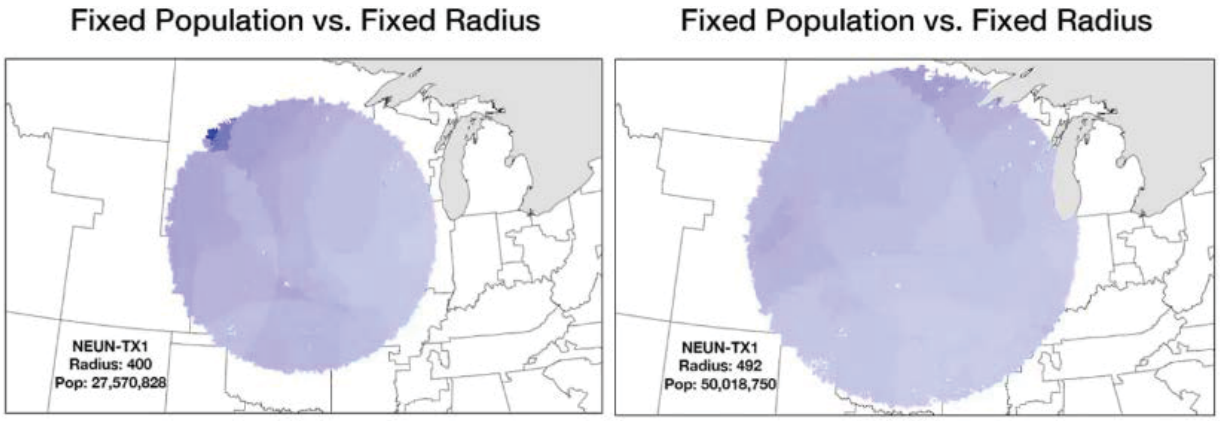
[10] 42 CFR 121.8(a)(2).
[11] 42 CFR 121.8(a)(5).
[12] Ibid.

Any proposal to incorporate circles into allocation policies should clearly define the relationship between the selection of the circle sizes and the Principles of Geography and the OPTN Final Rule. For example, the sizes of the circles could be based upon the distance when recovery typically changes from driving to flying because this impacts costs and the overall efficiency of the system. Alternatively, the size of a circle could be based upon the time when hospitals are typically unwilling to accept organ offers due to cold ischemic time because this impacts organ discard rates and organ utilization.

2. Mathematically optimized boundaries

The use of mathematical optimization in organ distribution has been discussed previously with the development of the changes to liver distribution. In this model, one or more objectives (minimize effect of geography, pre-transplant deaths, etc.) and possible constraints (amount of travel, supply and demand, etc.) are used to create the optimal distribution system. The Committee was presented with several models that utilize this approach including *Optimized Districts*, *Optimized Neighborhoods*, and *Population Density Bubbles*. The specifics of each model vary, however the goal of each is the same: to create an optimal geographic distribution area based on pre-determined metrics and constraints.

Figure 5: Example of Population Density Bubbles depicting the difference between a fixed radius circle (400 miles) and a fixed population circle (at least 50,000,000 population) around a transplant center[13]



[13] Sommer Gentry, "Fixed Population vs. Fixed Radius" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26 2018).

Figure 6: Representation of Organ Distribution Based on Optimized Districts

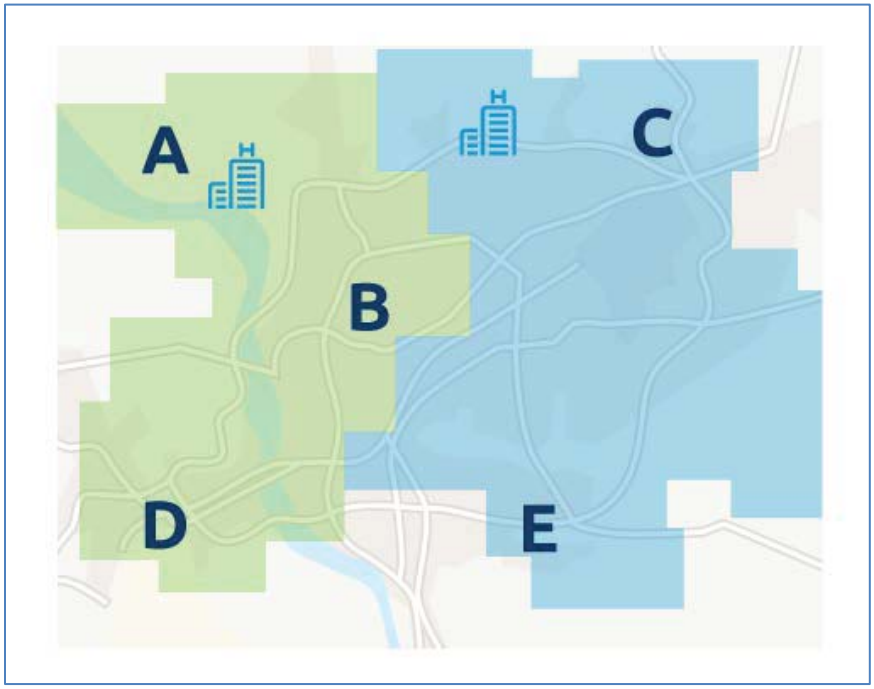


Figure 7: Representation of Organ Distribution Based on Optimized Neighborhoods

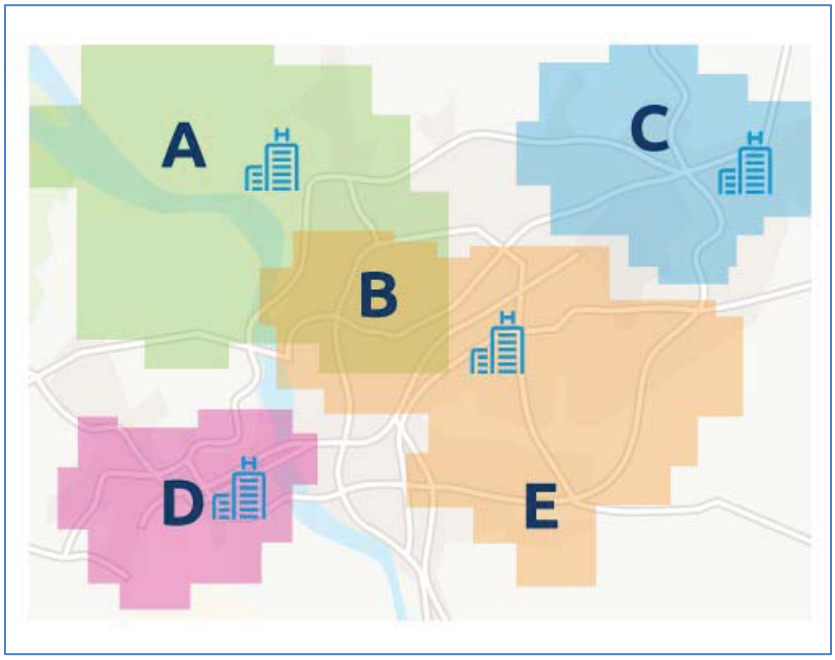
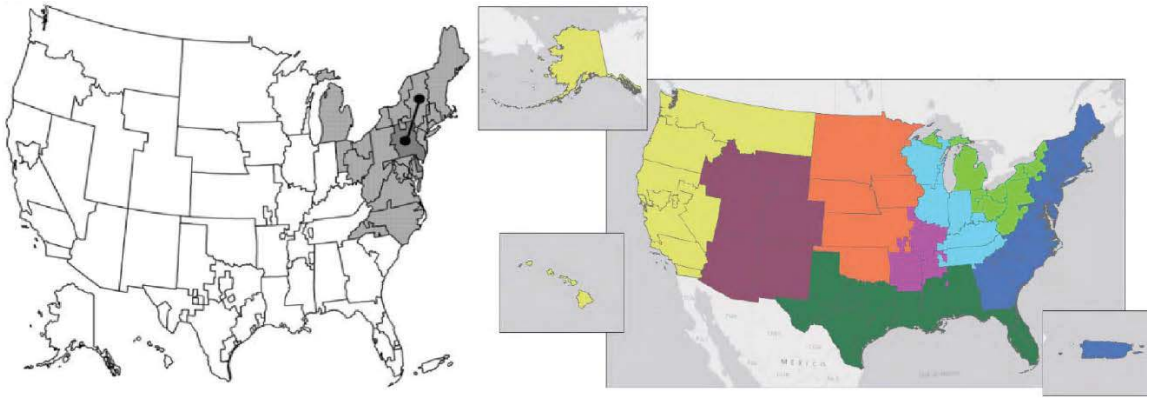


Figure 8: Example of Optimized Neighborhoods[14] and Optimized Districts[15]



The use of metrics and constraints to select the geographic distribution area reduces the concern for arbitrarily defined geographic borders of distribution. There is flexibility to allow organ-specific variation details due to variation in ischemic time and donor characteristics. As long as the input constraints are consistent with the Geographic Principles and the Final Rule, mathematically optimized units of distribution are ethically and legally defensible. Concern for system resources and efficient operation of the OPTN can be addressed by constraining the extent of organ travel and number of programs within any given geographical unit.

Hypothetically, most concerns for travel and logistics with this approach could be addressed in the optimization. However, optimized units have not been well-received by the community in the past.[16] Many versions of this model still retain fixed borders that create the possibility of two similarly situated candidates on either side of the border receiving different levels of access to organs. Additionally, optimized distribution models that utilize existing DSAs as a building block are fundamentally flawed given the variation in DSA characteristics (size, population density, etc.) throughout the country.

3. Continuous Distribution

The model of organ distribution without geographic boundaries incorporates proximity of candidates to a donor through an algorithm designed to account for the principles above (e.g. outcomes, discards, efficiency), rather than their location inside or outside a boundary.[17] The concept reviewed by the Committee proposed that candidates' *Allocation Priority Score* would be made up of a *Medical Priority Score* plus a *Proximity Score*. By using this kind of calculation, there would not be absolute geographic boundaries, and candidates would be ranked on a match run based on a combination of their clinical characteristics and proximity to a donor.

[14] Sanjay Mehrotra, PhD,Vikram Kilambi, PhD,Kevin Bui, MS,Richard Gilroy, MD, Sophoclis P. Alexopoulos, MD, David S. Goldberg, MD, MSCE, Daniela P. Ladner, MD, MPH, and Goran B. Klintmalm, MD, PhD; A Concentric Neighborhood Solution to Disparity in Liver Access That Contains Current UNOS Districts; Transplantation, February 2018, Volume 102, Number 2.
[15] *Redesigning Liver Distribution*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf (accessed July 5, 2018).
[16] "Redesigning Liver Distribution," OPTN, updated December, 2016, https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/. This page contains the comment received during the public comment period.
[17] Jon Snyder, "Systems without Geographic Boundaries" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26, 2018).

Figure 9: Example of Continuous Distribution

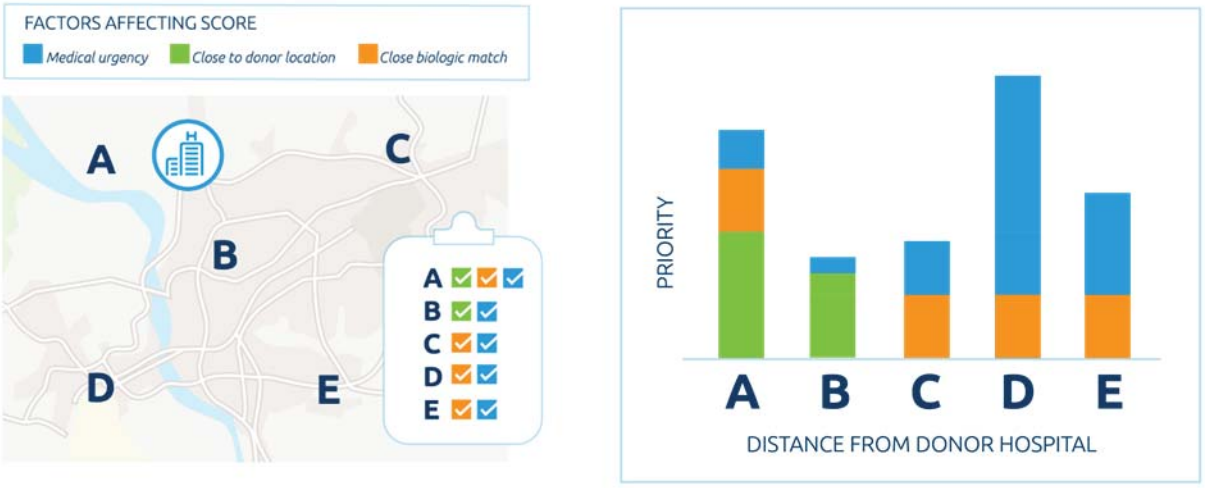
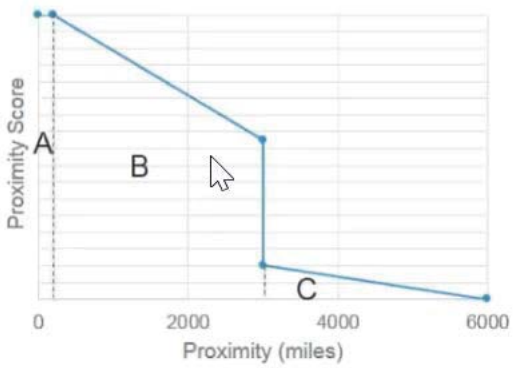


Figure 10: Depiction of the proximity score under the concept of distribution without boundaries

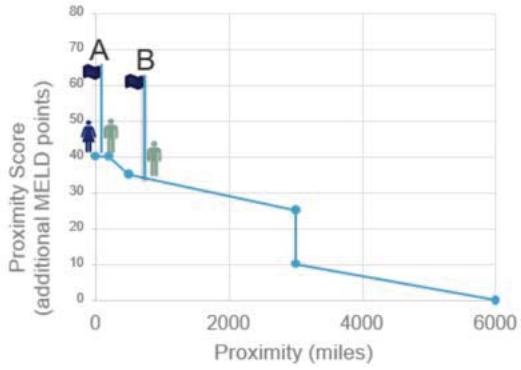


The Proximity Score Function likely has 3 zones:

Zone A: The "near the donor" zone

Zone B: Between "near" and "too far"

Zone C: Likely too far



Example of this function would work:

Patient A: MELD 25, 100 miles
Patient B: MELD 30, 750 miles

Patient A is offered before patient B using this function.

If we made Zone B shallower, Patient B could be offered prior to patient A.. this is the "value judgment".

The Committee discussed several advantages of this distribution model and its alignment with the principles. This model contains all of the benefits described in the fixed distance framework above. Additionally, this model can eliminate any concern over fixed geographic boundaries separating candidates and donors. This distribution model is theoretically similar to the idea of concentric circles and zones, except the fixed "cliff" that separates candidates in their respective zones would be a much more smooth transition, rather than an absolute boundary based on distance.

This model could be uniform across the organs and the medical priority and proximity scores could be specific to the clinical characteristics and ischemic considerations of each organ. This would require

significant discussion by the organ-specific stakeholders to identify the medical and geographic thresholds to prioritize candidates.

Alternatives Considered

The Committee reviewed several other distribution frameworks in their process to identify these final three. The review of other distribution frameworks focused on alignment with the Final Rule, and with the Committee's principles of geographic distribution. The Committee discussed the use of OPTN region and DSA and overwhelmingly stated that these geographic boundaries were not designed for the purposes of organ distribution and were an imperfect substitute for geographic proximity. The concept of a single national list was discussed and identified as a framework that is not in alignment due to the lack of efficiency in allocation, potential impact on discards, and the logistical concerns of a national list absent of any further constraints.

How well does this proposal address the problem statement?

The distribution frameworks included in this proposal represent the consensus of an ad hoc committee of transplant surgeons, physicians, OPO leadership, a donor family member, and a transplant recipient. The Committee consists of members of the OPTN/UNOS Board of Directors, representatives from AST and ASTS, and the leadership of the OPTN organ-specific committees, OPO Committee, Transplant Administrators Committee (TAC) and Ethics Committee.

The Committee believes the frameworks included in this proposal balance the requirements of the OPTN Final Rule, and are in alignment with the Principles of Geographic Distribution approved by the Board of Directors in June 2018.

Framework	Advantages	Disadvantages
Fixed distance	• Used in thoracic distribution. • Has been modeled. • Can address organ outcomes, system efficiency, and geographic disparities in access. • Can be organ specific. • Potentially easiest for general public to understand.	• "Cliffs" can separate similarly situated patients with minor geographic differences.
Mathematically optimized boundaries	• Has been modeled and published. • Can address organ outcomes, system efficiency, and geographic disparities in access. • Can be organ specific.	• Has not been used in organ distribution. • "Cliffs" can separate similarly situated patients with minor geographic differences.
Continuous Distribution	• "Cliffs" need not separate similarly situated patients with minor geographic differences. • Can address organ outcomes, system efficiency, and geographic disparities in access. • Can be organ specific. • Potentially most flexible model.	• Has not been modeled or used in organ distribution.

Which populations are impacted by this proposal?

This proposal and subsequent changes to organ distribution will affect every member of the transplant community.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no immediate impact to this goal. Changing to a uniform framework for distribution need not change the level of distribution in the system. It is possible, and even likely, that the development of organ specific policy proposals to align with a uniform framework will result in improvements in equity in access to transplantation.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* Once a single distribution model is chosen, the cost and time to program future distribution changes will decrease.

How will the OPTN implement this proposal?

Once the Board adopts a preferred distribution model, all future distribution proposals will be evaluated against that model. Committees will need to justify any distribution model that does not move toward the preferred distribution model. Depending upon available resources and priorities, the Policy Oversight and Executive Committees will prioritize requests to transition from the current distribution models to the preferred distribution model.

The broad purpose for a consistent framework is long term, efficiency as opposed to addressing an imminent, legal risk. Therefore, the OPTN does not need to all switch all of the organ systems to a consistent framework rapidly. Through separate projects, the OPTN is working to rapidly convert each of the organs systems to one of the three frameworks in this proposal.

The OPTN frequently makes changes to the allocation policies. As we review data and make future changes, we'll have a guidepost that all the committees can work toward. For example, if cliffs are bad, the committees can all take a similar approach to smoothing out cliffs. Which framework is preferred will impact the order and speed by which the OPTN can change the existing systems. For example, if circles are preferred, than heart and lung distribution is largely there. If mathematically optimized boundaries or continuous distribution are preferred, that's a different situation. In either situation, the Policy Oversight Committee and Executive Committee will review and prioritize these efforts.

How will members implement this proposal?

As this proposal does not change any member requirements, members will not need to do anything to implement this proposal. The details regarding member impact will be included in the analysis of any future, specific changes to the organ allocation systems.

EXHIBIT H

Analysis Report

Data Request on Circle Based Allocation

Date: 9/24/18

Prepared By:

Tim Weaver, MS; David Schladt, MS; Josh Pyke, PhD; Bryn Thompson, MPH; Alyssa Herreid, MPH; John R. Lake, MD; W. Ray Kim, MD; Jon Snyder, PhD; Bertram L. Kasiske, MD; Ajay K. Israni, MD; Sommer Gentry, PhD

Data Request ID#: LI2018_01

Timeline:

Committee met	July 10, 2018
Request made	July 19, 2018
Analysis plan submitted	August 1, 2018
Analysis report submitted	September 24, 2018
Next Committee meeting	September 25, 2018

Table of Contents

Executive Summary

SRTR has used the liver simulated allocation model (LSAM) to assess the simulated impact of two allocation frameworks based on concentric circles around the donor hospital: "Acuity Circles" (AC) and "Broader 2-Circle Distribution" (B2C).

What's New in This Report

- Relisted candidates are now included in "by MELD/PELD" calculations for counts and rates of waitlist mortality and transplants.
- A finer resolution is used for person-time (denominator) in the rate calculations; previous reports' calculations were rounded to whole days, whereas now fractional days are used. As a result, some of the rates calculated by DSA for small subgroups (e.g., pediatrics) were much larger than they were previously. Before these rates were used in the variance by DSA calculations, they were capped at the 99th percentile of all subgroups across all DSAs (e.g., 14.6 transplants per patient-year for patient age) to prevent overinflated variances.

Main Findings

The B2C scenarios yielded results similar to those under the policy approved by the UNOS Board in December 2017. Specifically, the variance in median allocation MELD/PELD at transplant (MMAT) decreased to a similar extent, and the transport metrics (transport time, transport distance, and percentage of organs flown) increased to a similar extent.

Compared with the current allocation policy, the AC framework tended to result in changes with a larger magnitude than the B2C framework; i.e., of all scenarios considered, the AC scenarios showed the largest decreases in variance of MMAT and the largest increases in the transport metrics.

MELD scores at transplant: Both proposed frameworks reduce variance in DSA level MMAT (Figure 1). The reduction in variability is due to increasing MMAT for DSAs with lower MMAT under the current framework (Figure 3); this corresponds to changes from "warm" to "cool" colors on the maps. The increase in MMAT also occurred nationally, driven largely by the "No Exception" group of candidates (Figure 2).

Transplant rates and counts: Transplant rates and counts were not affected by the new frameworks for the overall population or by exception status. Rates increased for high MELD/PELD (≥ 32) candidates for both frameworks (Figure 6).

Waitlist mortality rates and counts: Waitlist mortality rates decreased for the overall population under the AC framework driven largely by candidates without exceptions (Figure 11), while the B2C framework showed a more modest change.

Waitlist mortality counts decreased for high MELD/PELD (≥ 32) candidates in both frameworks (Figure 14).

Post-transplant mortality rates and counts: Post-transplant mortality was comparable between the different frameworks (Figures 18-21).

Transport metrics: Both of the new frameworks resulted in more travel; greater transport distances and times accomplished through a higher percentage of organs being transported by air

(Figures 22-29). A similar trend between the different frameworks is consistently seen across metrics and exception and MELD groupings.

Subgroup analysis: At a regional level (Appendix A), for most metrics, the different frameworks showed no impact (i.e., flat line of dots), or showed the same trend as the national population. Transplant rates by exception status were the exception to this, with some regions seeing slight increases or decreases in the rate, whereas the national population had essentially uniform transplant rates between frameworks.

Overall, trends in the demographic characteristics' (age, sex, and race/ethnicity) subgroups were similar between frameworks to the total population (Appendix B). The exception to this was the pediatric subgroup, which saw reductions in MMAT (Figure 242) and increases in transplant rate (Figure 245) that differed directionally from the overall population. The trends in the transportation metrics were common across age ranges (adult and pediatric).

The trends for the socio-economic status characteristics (education, insurance type, cumulative community risk score, and urbanicity) subgroups were similar between frameworks to the total population (Appendix C).

Study Population

Data for these policy simulations were collected between July 2013 and June 2016, post-Share35 implementation. The simulation uses donor and candidate populations created by the LSAM donor and candidate generators. This software draws on patient data for transplant candidates listed at the beginning of the data cohort period, and candidates added to the waiting list and organs donated during the data cohort period. The generators use these real patient data to create independent donor and candidate populations for each of the multiple LSAM iterations involved in simulating each allocation scenario.

Analytical Approach

Policy scenarios

The policy scenarios simulated as part of this request are shown below:

Scenario 1 - Current System: Uses current distribution and allocation order ("Share 35" with MELD sodium and HCC cap and delay). No proximity points are included, and there are no donor exclusions.

Scenario 2 - Board Approved: Candidates with a MELD score of at least 15 and listed at centers within either (a) the DSA of the donor hospital or (b) a 150-nautical-mile radius circle from the donor hospital receive three additional proximity points added to their lab MELD for adults and their allocation MELD/PELD for candidates aged younger than 18 years, with a sharing threshold of MELD/PELD $\geq$ 32.

Proximity points are defined as follows: At the time of the match run, liver candidates with MELD or PELD scores of 15 or higher, and registered at a transplant hospital within a 150-mile radius of the donor hospital, or within the same DSA as the donor hospital, receive three MELD or PELD points added to their score as described above.

For adults, proximity points are only added to calculated (lab) MELD score. For candidates younger than 18, proximity points are added to the allocation MELD/PELD score.

Note: The summation of calculated MELD scores plus proximity points will not be capped at 40; a candidate with a calculated MELD score of 38 who receives three proximity points will be given an adjusted MELD score of 41 to preserve ranking of disease severity.

Scenario 3 - Acuity Circles (250 and 500 nautical miles): Uses three concentric circles around the donor hospital with radii measured in nautical miles: small = 150nm, medium = 250nm, and large = 500nm.

Status 1A and 1B are allocated first at centers within the large circle, and then allocation proceeds in expanding circles (small, medium, large) for each decreasing MELD/PELD subgroup: at least 37, [33,37), [29,33), [15,29).

Centers outside of the large circle are allocated next for: status 1A, status 1B, and then MELD/PELD of at least 15.

Finally, candidates with MELD/PELD less than 15 in expanding circles, and outside of the large circle.

Scenario 4 - Acuity Circles (300 and 600 nautical miles): Scenario 4 uses the same rules as scenario 3 with small, medium, and large circle sizes of 150, 300, and 600 nautical miles, respectively.

Scenario 5 - Broader 2-Circle Distribution (MELD Threshold = 35): Uses three concentric circles around the donor hospital with radii measured in nautical miles: small = 150nm, medium = 250nm, and large = 500nm.

Status 1A and 1B are allocated first at centers within the large circle, and followed by those within the medium circle with a MELD/PELD of at least the threshold of 35.

Allocation then proceeds in expanding circles (small, medium, large) for those with MELD/PELD of at least 15.

Centers outside of the large circle are allocated next for: status 1A, status 1B, and then MELD/PELD of at least 15.

Finally, candidates with MELD/PELD less than 15 in expanding circles, and outside of the large circle.

Scenario 6 - Broader 2-Circle Distribution (MELD Threshold = 32): Scenario 6 uses the same rules as scenario 5 with a MELD threshold of 32.

Metrics

SRTR assessed the following outcome metrics for the simulations:

1. Variance in median MELD/PELD at transplant by DSA
2. Median MELD/PELD at transplant
3. Transplant rates
4. Transplant counts
5. Variance in transplant rates by DSA

6. Wait list mortality rates
7. Wait list mortality counts
8. Variance in wait list mortality rates by DSA
9. Post-transplant mortality rates
10. Post-transplant mortality counts
11. Median transport time
12. Median transport distance
13. Percentage of organs flown for transport

Metrics 1 to 13 above will be assessed by subgroup populations including:

- Exception status: total, no exceptions, HCC exceptions, other exceptions
- MELD/PELD subgroups: <15, 15-24, 25-28, 29-31, 32-35, 35+ (includes Status 1A and 1B)

Color-coded maps displaying the following metrics by DSA are also included:

2. Median MELD/PELD at transplant
3. Transplant rates
4. Wait list mortality rates
5. Percentage of organs flown for transport (by both donor and transplant DSA)

The above metrics excluding those that measure variance by DSA (1, 5, 8) were assessed by OPTN region

- OPTN region: 01-11
  - By exception status
  - By MELD/PELD subgroup

Metrics 1 to 10 above were assessed by the additional subgroup populations including:

- Age: pediatric (aged younger than 18 years at listing) and adult (≥ 18 at listing)
- Sex: female and male
- Race/ethnicity: African American, Asian/Pacific Islander, Hispanic, white
- Education: high school or less, more than high school
- Insurance status: public and private
- Urbanicity: metropolitan, non-metropolitan, micropolitan, small town, rural
- Cumulative Community Risk Score (CCRS) subgroups: [0,10], (10,20], (20,30], (30,40]

Additionally, spreadsheets with the following metrics by DSA are included:

2. Median MELD/PELD at transplant
3. Transplant rates
4. Transplant counts
5. Wait list mortality rates
6. Wait list mortality counts
7. Percentage of organs flown for transport (by both donor and transplant DSA)

PAGES 6-320 SUPPLIED IN ELECTRONIC FORMAT

The Analysis report contains a 5 page report, 31 pages of results depicted via data charts, and a 284 page appendix. The analysis of findings, pages 1-5 of the Analysis Report, is attached to this filing in hardcopy. The entire report is being provided be provided to the Commission and all parties in electronic copy.