

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.

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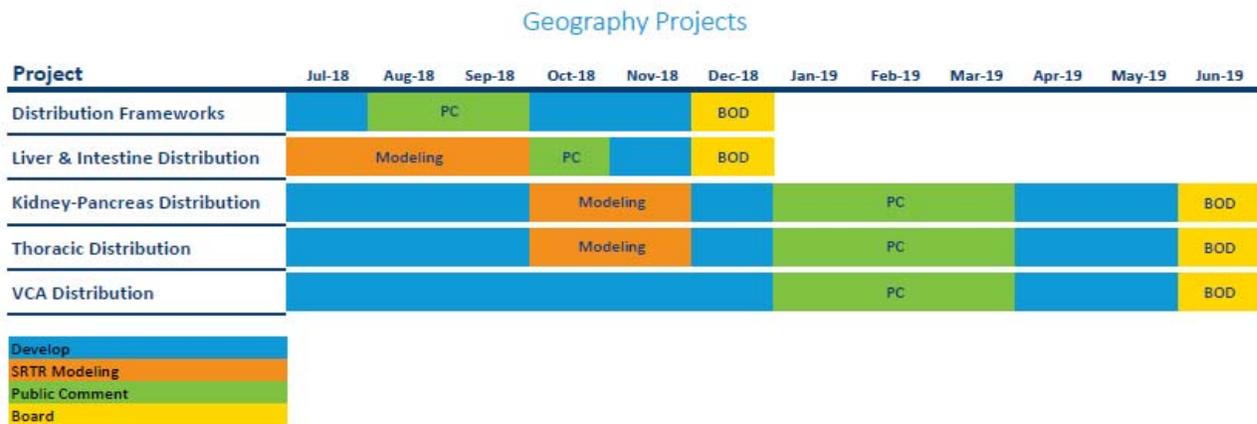
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The chart below summarizes the timeframe for completing this work.



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.