

Update from Yolanda Becker, M.D., re: OPTN and liver distribution

Date: June 27, 2018

From: Yolanda Becker, M.D., President, OPTN/UNOS Board of Directors

To: Transplant program directors
Transplant program administrators
OPO chief executive officers/executive directors
OPO procurement administrators/managers
HLA laboratory directors

As we mentioned to you in an e-mail June 20, UNOS received a letter from HRSA asking us to respond to a critical comment sent to HHS under the terms of the OPTN Final Rule. That critical comment came from the same law firm that filed suit in federal court in 2017, ultimately resulting in an emergent change to lung distribution policy. This critical comment addresses concerns with liver distribution policy, emphasizing the role of the local donor service area (DSA) as a part of the liver policy.

The OPTN/UNOS Executive Committee responded to HRSA as requested on Monday, June 25. Our full reply is attached for your reference.

Our goals are two-fold:

1. To defend the new liver policy and the work of the Liver and Intestinal Organ Transplantation Committee
2. To protect our community's decision-making ability by revising policy with a replacement for the use of DSA and regional boundaries as quickly as possible

Both of these goals are designed to ensure that decisions are data-driven and include community input on changes to allocation policy by following as much of our regular process as possible.

The below excerpt from the letter's executive summary outlines the basis of our response:

The OPTN has conducted a review as requested including consultation with the Liver and Intestinal Organ Transplantation Committee and Policy Oversight Committee and has determined that the revised Liver Policy does not include an over-reliance on DSA as the primary unit of liver distribution because the most medically urgent patients are prioritized regardless of whether they are located within or outside of the DSA where the liver becomes available.

Accordingly, the incorporation of DSA in the revised Liver Policy is materially different than the use of DSA in the prior Lung Allocation Policy that shared first exclusively within the DSA. Nonetheless, the OPTN previously recognized and again confirms 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 for all candidates. Accordingly, the OPTN is committed to a multi-step plan to eliminate the use of DSAs in the distribution of livers in a deliberative process and timeframe that will reduce the likelihood of unintended consequences including the significant potential for increased organ wastage or harm to patients waiting if a precipitous change were made to the revised Liver Policy without the benefit of any modelling and stakeholder input.

The Executive Committee has directed the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee to review available data and propose, consistent with the Final Rule

and the recently adopted OPTN principles of distribution, a liver policy that replaces the DSA and region as distribution units.

The OPTN will publicize any available data or modeling available and will seek public feedback on a resulting proposal. This feedback will likely take place in a special public comment period in October or November 2018. The OPTN/UNOS Board, at its December 2018 meeting, will review and vote on a resulting proposal.

It is too soon to say with certainty how these actions will affect previous plans to implement the liver distribution system originally approved by the Board at its December 2017 meeting. We will continue to assess these developments and will keep you informed to the soonest and greatest degree possible.

This is a pivotal time for the field of organ transplantation in the United States. Please know that our community's ability to act now, in a constructive fashion, may be our last and best opportunity to allow us to keep making decisions as a community rather than have them decided by judicial or legislative means.

We appreciate your attention and will continue to keep you posted.