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TO: George Sigounas, MS, Ph.D.
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FROM: Yolanda Becker, MD
President, OPTN/UNOS Board of Directors

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

DATE: June 25, 2018

RE: Review of Liver Allocation Policy by the OPTN/UNOS Executive Committee

Executive summary:

On behalf of the United States Department of Health and Human Services (HHS), on June 8, 2018, Health Resources and Services Administration (HRSA) Administrator George Sigounas, on behalf of HHS, sought the views of the Organ Procurement and Transplantation Network (OPTN) on whether aspects of the revised OPTN Liver Allocation Policy adopted by the Board of Directors in December 2017 and scheduled for implementation in December 2018 (the "revised Liver Policy") are consistent with the requirements of NOTA and the OPTN final rule. Specifically, the OPTN was requested to comment on the following in regard to the revised Liver Policy: (1) use of Designated Service Areas (DSAs) as units of allocation; (2) use of OPTN regions as units of allocation, alone or in combination with a circle originating from donor hospitals; (3) use of proximity points in relation to DSAs; and (4) use of median MELD in DSAs in granting exception points to transplant candidates. The OPTN was also asked to address any rationale supporting utilization of DSAs in any of the above-described aspects of the revised Liver Policy as distinguishable from the OPTN's position regarding use of DSA in the previous Lung Allocation Policy.

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.

1. *Use of DSAs in the revised Liver Policy*

It is important to recognize that the issues raised in the OPTN's review of distribution of lungs in November 2017 are distinguishable from those identified in the letter dated May 30, 2018, criticizing the use of the DSA in the revised Liver Policy. Significantly, DSA was the exclusive primary unit of lung distribution in November 2017 when the OPTN was directed to review and comment on the lung policy. At that time, the OPTN concluded that the exclusive reliance on DSA for lung distribution constituted an "over reliance" on DSA and that "a policy that does not depend on DSA as the primary unit of allocation of lungs is more consistent with the Final Rule than a policy that shares first exclusively within the DSA." In contrast, the revised Liver Policy does not utilize DSA as the primary unit of distribution but rather distributes livers first to the most medically urgent candidates (Status 1A, 1B and candidates with a calculated MELD/PELD of at least 32) anywhere within 150 nautical miles of the donor hospital regardless of whether those candidates are in the same DSA or OPTN Region as the donor. In addition, livers are offered to candidates anywhere in the same OPTN Region as the donor. Accordingly, the revised Liver Policy does not rely on the DSA as the primary distribution unit.

The revised Liver Policy is based on sound medical judgment by prioritizing medically urgent candidates, seeks to achieve the best use of donated organs, is designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement. For example, the revised Liver Policy includes a separate allocation sequence for donation after cardiac death (DCD) donors and donors at least 70 years old. Livers from this subset of donors are initially allocated to candidates with the greatest medical urgency in the OPTN Region or circle (Status 1A and 1B), before being allocated to candidates with a MELD/PELD of at least 15 in the DSA. Data shows that this subset of donor organs are more likely to be discarded, but are also more likely to be transplanted within the DSA.[1]

[1] Enhancing Liver Distribution Briefing Paper, available on the OPTN Website

Further, the revised Liver Policy was developed after extensive simulation modeling with a goal to reduce wide variations in access to transplantation experienced in different parts of the United States. Based on this modeling, the revised Liver Policy is predicted to reduce the disparity in access to transplant by 26%, represented by the variance in median allocation MELD/PELD at transplant among DSAs.[2] The revised Liver Policy accomplishes this with smaller increases in cold ischemic time and transportation costs than other models that were evaluated.[3]

The geographic distribution of livers may appropriately be constricted to avoid organ wastage and to promote the efficient management of organ placement, consistent with the OPTN Final Rule[4]. While the use of DSAs has historically been relied upon for those purposes, the OPTN acknowledges the importance of 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. This effort is currently underway through the OPTN Geography Committee's work (described in the "Next Steps" section below).

2. *Using OPTN regions as units of allocation, alone or in combination with a circle originating from donor hospitals*

The Revised Liver Policy includes OPTN Regions as a geographic unit of allocation for several reasons:

- Over the last decade, the OPTN has progressively broadened liver distribution within the OPTN Regions. Beginning with regional allocation to Status 1A and 1B candidates in 2010, followed by the implementation of "Share 35" in 2013 which broadened allocation to candidates with a MELD/PELD of at least 35. The revised Liver Policy is an extension of this broadening of regional distribution to a larger subset of medically urgent candidates (MELD/PELD of at least 32). Additionally, the 150 nautical mile circle around the donor hospital overcomes Regional boundaries that separate donors from medically urgent candidates within close proximity.
- Several OPTN Regions are geographically larger than many of the potential circle sizes considered during development of the Revised Liver Policy. A distance-based circle around a geographically isolated donor hospital could have reduced distribution compared to the existing OPTN Regions.
- Geographically isolated programs in Hawaii and Puerto Rico are included in the current OPTN Regions but would be uniquely negatively affected by a distribution system based solely on circles.
- Regions are used in the allocation of all abdominal organs, including SLK allocation.

However, like DSAs, OPTN Regions are an imperfect substitute for proximity between the donor and candidates. Moving towards a framework that utilizes a more consistent and direct

[2] SRTR analysis requested by HRSA and submitted February 16, 2018
[3] SRTR analysis requested by the Liver and Intestine Committee and submitted May 1, 2017
[4] 42 C.F.R. § 121.8

measure of distance to appropriately address cold ischemic time and transportation costs is anticipated with the process underway by the OPTN Geography Committee.

3. Using proximity points in relation to DSAs

After allocating livers to the highest priority patients within the OPTN Region and circle, the revised Liver Policy grants an additional advantage by awarding three MELD/PELD proximity points to candidates within 150 nautical miles of the donor and to candidates within the same DSA as the donor to mitigate travel for small differences in medical urgency. The revised Liver Policy provides these points to candidates within the DSA because the 150-mile circle is smaller than the DSA in several areas of the country. Providing proximity points only to candidates within the circle would therefore have the effect of prioritizing candidates at certain programs in the DSA over other candidates located within the DSA but outside the circle.

Consistently awarding proximity points in order to reduce cold ischemic time and transportation costs through the 150 nautical mile circle is consistent with the OPTN Final Rule. However, because of the variation in DSAs across the country, the use of DSAs are not optimal units of geography to represent proximity between a donor and candidates to determine the award of proximity points to specific candidates. It is likely that broader sharing of more livers will result in transporting livers greater distances to reach candidates who may have small differences in medical urgency compared to candidates who are geographically closer to the donor. Moving to a framework that utilizes a more consistent and direct measure of distance to appropriately mitigate the cost and inefficiency of travel for small differences in medical urgency is anticipated with the process underway by the OPTN Geography Committee.

4. Using median MELD in DSAs in granting exception points to transplant candidates

Exception policies have been developed to ensure fair access to those candidates for whom the calculated MELD/PELD score does not accurately capture their medical urgency. It is important that the award of exception points be made in the context of the other candidates who might receive the same organ offers as the exception candidate. To the extent liver allocation policies use DSA as a unit of allocation, it is appropriate to consider the scores of the other candidates in that DSA in determining an exception score in order to appropriately balance prioritization between exception and non-exception candidates. However, when liver allocation policy is further revised to eliminate the use of DSA as a component of distribution as outlined below, the replacement tool for determining the geographic unit of proximity for candidates with which to compare an exception candidate will need to be changed concurrently.

Work Underway and Next Steps

As you recognized, the OPTN took immediate action after the December 2017 Board meeting to establish an ad hoc Geography Committee tasked with:

1) Establishing principles of organ distribution consistent with the Final Rule (adopted by the Board June 2018)
2) Identifying proposed allocation policy frameworks consistent with the principles of organ distribution and the Final Rule (completed by the Geography Committee May 2018)
3) Seeking comment on the proposed policy frameworks (anticipated Fall 2018)

Ultimately, the goal is to identify a single framework that once implemented over time will provide consistency across all organ types regarding how the organ allocation system incorporates geographic constraints consistent with the mandates of NOTA and the Final Rule.

We recognize that the potential for harmful unintended consequences of implementing precipitous changes to the distribution of livers (such as the immediate elimination of DSA as an element of distribution) could be significant to patients, without careful review and consideration of appropriate alternatives for geographic restriction. Specifically, we are concerned that replacing DSA with another constraint that has not been carefully modeled carries the potential risk of decreased organ utilization (i.e. percentage of organs procured from donors of at least one organ) and/or increased organ discard (i.e. percentage of procured organs that are not used for transplant) due to the added complexity of including multiple OPOs and transplant centers in the procurement process.

As of June 18, 2018, there are 13,892 candidates waiting for a liver transplant. Liver allocation policy impacts liver, liver-intestine, and simultaneous liver and kidney (SLK) allocation systems. A deliberate, step-wise approach to further revising the liver allocation policy in a prompt but reasonable time-frame to eliminate reliance on DSA and OPTN Region and replace with elements consistent with the newly adopted geographic principles of distribution will best ensure compliance with the Final Rule and reduce the potential for harm.

Accordingly, the OPTN Executive Committee is implementing the following plan to eliminate DSA or OPTN Regional boundaries as a component of distribution and utilize a different tool for incorporating proximity restrictions consistent the newly adopted geographic principles of distribution:

1) The Executive Committee will direct the OPTN Liver and Intestinal Organ Transplantation Committee to review available data and propose consistent, Final Rule-compliant replacements for DSA and region in liver allocation policy.
2) The OPTN will release any available data or models for public discussion and feedback. In order to allow the Liver Committee time for careful review, this discussion will likely take place in a special public comment period in October or November, 2018.
3) The OPTN Board of Directors will adopt a replacement for DSA and OPTN Region in liver allocation policy at its meeting in December 2018.
4) The policy approved by the OPTN Board of Directors in December will be expeditiously implemented in the matching IT system.

The OPTN will provide HRSA with quarterly updates as this plan progresses.

Once implemented the OPTN will monitor the effects of the policy change on liver candidates by medical and demographic characteristics, and monitor for any unintended consequences such as poorer graft survival, increased discards, or increased costs.