OPTN/UNOS Ad Hoc Geography Committee Meeting Minutes Conference Call July 3, 2018

Kevin O'Connor, MS, PA, Chair

Introduction

The Ad Hoc Geography Committee met via teleconference on 07/03/2018 to discuss the following agenda items:

- 1. Introductions and Announcements
- 2. Board of Directors Meeting and Critical Comments Update
- 3. Next Steps

The following is a summary of the Committee's discussions.

1. Introductions and Announcements

The Chair welcomed everybody to the call and thanked them for joining on such short notice.

2. Board of Directors Meeting and Critical Comments Update

The Board of Directors considered and adopted the principles recommended by the committee at their meeting in June by a vote of 33-5.

The Final Rule includes a process where the public can comment which creates a secretarial review. The Secretary has the option of rejecting the comments, directing OPTN to revise policies, or other actions as appropriate. This review was initiated by a letter from a New York attorney regarding the liver policy. While a review was being conducted more letters were received regarding the policies. HRSA requested a review from OPTN whether these met NOTA and the Final Rule. The OPTN responded on June 25th that liver was different from lung, with no over reliance on DSA in liver that existed in lung. The Executive Committee reconfirmed that DSA and regions are not ideal proxies for the nearness of the donor to the candidate, and Final Rule allows us to include geography to promote organ quality, to promote organ utilization, reduce wastage, and promote efficiency.

On June 27th OPTN/UNOS Board of Directors President notified the transplant community the goals are to defend the new liver policy and work of the committee, and that the committee will begin work on a replacement for DSAs and regions as quickly as possible.

Next Steps for Liver

There is a liver committee meeting this afternoon and they will be requesting models of options. After model and data review, discussions will be held in the regional meetings leading to a formal proposal for a virtual public comment cycle in October. This public comment period will include webinars for the online sites and other methods to collect feedback about particular models. A proposal for replacing DSAs and regions will be developed for the Board of Directors to approve at the December meeting. IT will follow the work of the committee and prepare for implementation soon after the December Board meeting.

Discussion

With regards to the liver policy, although a number of letters have been received, they may not be considered critical comment by the Secretary. This shouldn't change the legal strategy and reinforces that the committee is on the right track for change. The bottom line is we need to

eliminate the DSA and regions as units of distribution because it's not in alignment with the Final Rule.

3. Next Steps

The use of DSA and regions for distribution purposes are not limited to liver and lung but used in some aspect by all organ allocation systems. Discussions are ongoing with leaders of organ-specific committees about creating a project proposal to address use of DSA and regions across all organs. A goal is to work with liver to put together a modeling request in the next few weeks. SRTR will provide modeling prior to special public comment on liver changes this October. Then the proposal will be presented to the Board for adoption. The organ-specific committees will begin work on three projects: heart and lung need the same distribution levels, kidney-pancreas community will address the use of DSA and regions, and talks will be conducted with the VCA community about removing regions from their allocation sequence. SRTR will help with modeling this fall that is scheduled to go out for public comment in the spring of 2019 with the final plan to go before the Board for their June 2019 meeting. This will resolve the use of DSA and regions throughout all policies by the summer of 2019.

The Geography Committee will continue to convene during that timeframe with an oversight role and continue to receive updates from the committees while encouraging them to maintain focus and keep moving forward. The committee can also help shape conversations and ensure consistency across different organ systems as proposals are being developed.

There is a plan for the Geography Committee to release a public comment proposal this fall for the types of distribution models. Three proposals will be put out for feedback with the goal of selecting one model for distribution to be used across all organs. We are focusing on liver modeling right away because that's the highest risk right now getting that out for special public comment this October. As soon as the modeling is received from SRTR for liver modeling, requests will be submitted for all other organs to get those out for public comment in January of next year. Liver changes will go to the Board in December and that information will be used for public comment next year for all organ systems.

A scheduling request will be sent out soon for future Geography Committee calls.

Peter Goldin is new on-staff and will be the staff analyst for this committee moving forward.

Upcoming Meetings

- July 24, 2018
- August, 28, 2018