# OPTN/UNOS Policy Oversight Committee Meeting Minutes January 17, 2018 Conference Call

# Jennifer Milton, BSN, CCTC, MBA, Chair Elizabeth Pomfret, MD, PhD, Vice Chair

### Introduction

The Policy Oversight Committee (POC) met by Citrix GoTo on January 17, 2018 to review a new proposed project from the Kidney Committee and to review 12 public comment proposals to make a recommendation to the Executive Committee about whether or not the proposals are ready for public comment. The following is a summary of the Committee's discussions.

# 1. Committee Projects

The POC has no currently active Committee projects.

# 2. Other Significant Items

## Public Comment Review:

The POC reviewed the following 12 Committee public comment proposals to make a recommendation to the Executive Committee about their readiness for public comment:

- 1. Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs (VCA Committee)
- 2. Broader Distribution of Adult Donor Lungs (Thoracic Committee)
- 3. Informed Consent Clarification for Transmittable Conditions (Ad Hoc Disease Transmission Advisory Committee)
- 4. Guidance on Requested Deceased Donor Information (OPO Committee)
- 5. Extra Vessels Reducing Reporting Burdens and Clarifying Policies (Operations and Safety Committee)
- 6. Guidance on Optimizing VCA Recovery from Deceased Donors (VCA Committee)
- 7. Hypertrophic Cardiomyopathy Restrictive Cardiomyopathy Exception Request Guidance for Review Boards (Thoracic Committee)
- 8. Maximum Allowable BMI for KP Waiting Time (Pancreas Committee)
- 9. Modification of the Lung Transplant Follow-up Form (TRF) to Include CLAD (Thoracic Committee)
- 10. OPTN Bylaws Revisions of Appendix L (Membership and Professional Standards Committee)
- 11. Standardizing Treatment According to OPTN Allocation Criteria (Ethics Committee)
- 12. Update Guidance for ABO Subtyping Organ Donors For Blood Groups A and AB (Operations and Safety Committee)

As part of the review process, POC members were divided into 4 groups and each reviewed three public comment proposals and completed a RedCap survey about each of their assigned proposals. Using the results of the survey, the POC liaison and leadership created consent and discussion agendas as follows:

## **CONSENT AGENDA:**

- 1. Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs (VCA Committee)
- 2. Informed Consent Clarification for Transmittable Conditions (Ad Hoc Disease Transmission Advisory Committee)
- 3. Extra Vessels Reducing Reporting Burdens and Clarifying Policies (Operations and Safety Committee)
- 4. Hypertrophic Cardiomyopathy Restrictive Cardiomyopathy Exception Request Guidance for Review Boards (Thoracic Committee)
- 5. Maximum Allowable BMI for KP Waiting Time (Pancreas Committee)
- 6. Modification of the Lung Transplant Follow-up Form (TRF) to Include CLAD (Thoracic Committee)
- 7. OPTN Bylaws Revisions of Appendix L (Membership and Professional Standards Committee)
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## **DISCUSSION AGENDA:**

- 1. Guidance on Optimizing VCA Recovery from Deceased Donors (VCA Committee)
- 2. Guidance on Requested Deceased Donor Information (OPO Committee)
- 3. Broader Distribution of Adult Donor Lungs (Thoracic Committee)

The POC addressed the consent agenda first and after very little discussion, the POC voted unanimously (12-0-0) to recommend that the nine proposals on the consent agenda move forward to public comment. The POC Chair also pointed out that two concept papers will be released this public comment cycle: one from the OPO Committee on Expedited Organ Placement and one from the Executive Committee on Improving the OPTN/UNOS Committee Structure. In addition, a revised 2018-2021 OPTN Strategic Plan will also be released for public comment in January.

The Committee then moved on to the discussion agenda. The POC voted unanimously (12-0-0) to recommend to the Executive Committee that these two proposals move forward to public comment:

- 1. OPO Guidance on Requested Deceased Donor Information (OPO) Comment from Committee member: The overall guidance reads too much like policy language and might be interpreted as requirements not guidance. Doesn't object to sending it for public comment, but could this be addressed post public comment?
- Guidance on Optimizing VCA Recovery from Deceased Donors (VCA) Comments from Committee member:
  - This project is not "maximum bang for the buck." Affects very few people.
  - This project is necessary because now that VCA is considered an organ according to the Final Rule, we have to try to align these policies with other organs.

There was significantly more discussion on the Broader Distribution of Adult Lungs proposal. After a lengthy discussion, the POC ultimately voted to recommend (6 Yes, 4 No, 2 Abstain) that the Broader Distribution of Adult Donor Lungs proposal move forward to public comment. Themes of the discussion and Committee member comments included:

- As a POC member, I was not even aware that this policy had gone forward already. Did this meet the policy development process? The entire policy development process was usurped and this has far-reaching implications.
- Why was this done in a rush over a 3-day holiday weekend?
- What's to stop others from doing this? We (UNOS) should have fought this; to redraw
  the DSA lines is very complicated and UNOS is failing to back-up their policies when
  they do this.
- If we expedite policies like this, why have the POC? Why am I reviewing and voting?
- Are the other organ allocation systems at risk for law suits because of this?
- Moving forward, the key is to have policies that are defensible, that is clear. But worries about having done this so quickly.

A few Committee members also expressed the concern that they were merely "rubber stamping" these proposals and that their expertise was not really needed and their comments were not really desired. The POC Chair wrapped up the discussion by assuring the Committee that she would voice their concern to the Executive Committee at their call to approve these public comment proposals the next day.

<u>Project Review: Improving Access for Pediatric & Highly Sensitized Kidney Candidates (Kidney Committee)</u>

Because of the lengthy discussion of the Broader Distribution of Adult Donor Lungs proposal, the Committee ran out of time and did not get to this agenda item. This project will be reviewed at the POC's February conference call instead.

The meeting adjourned at 4:38 PM.

# **Upcoming Meetings:**

- Friday, February 16, 2018, 3:00 PM ET
- Wednesday, March 21, 2018, 3:30 PM ET