

**OPTN/UNOS Policy Oversight Committee (POC)  
Meeting Summary  
September 12, 2014  
Conference Call**

**Yolanda Becker, MD, Chair  
Sue Dunn, RN, BSN, MBA, Vice Chair**

*Discussions of the full committee on September 12, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>.*

**Review of Public Comment Proposals**

Chair Yolanda Becker began with an overview of the POC's role in reviewing and evaluating Committees' public comment proposals, confirming that the most important decision to make is if the proposal is ready for public comment. She assured the Committee members that their comments captured in the survey they completed will be forwarded to the sponsoring Committee through the liaison and hopefully the Vice Chair who is on the call today. The comments collected during the survey are available on the POC sharepoint site.

The public comment proposals were grouped based on the survey results into a consent and discussion agenda as follows:

**Consent Agenda:**

GROUP 1: Thoracic: Collect ECMO Data at Removal for Lung Candidate

GROUP 1: POC: Multi-Organ Allocation

GROUP 1: Histo: Histocompatibility Bylaws Rewrite: Phase 2

GROUP 1: VCA: VCA Implementation

GROUP 1: KPD: KPD Informed Consent Guidelines to Policy

GROUP 1: OPO: Deceased Donor Registration Form Completion

GROUP 2: MPSC: Composite Pre-Transplant Metrics

GROUP 2: OSC: Develop Policy to Address Safety Concerns r/t Large Volume Waitlist Transfers

GROUP 2: MPSC: Definition of a Transplant Hospital

GROUP 2: KPD: KPD - All Other Guidelines to Policy

GROUP 2: POC: Definition of the End of a Transplant

GROUP 3: POC: Policy Rewrite Quick Fixes

GROUP 3: Peds: Pediatric Classification for Liver Candidates Turning 18

**Discussion Agenda:**

GROUP 2: VCA: VCA Data Collection and Submission

GROUP 3: MPSC: Quality Assurance & Process Improvement Initiatives

GROUP 3: Executive: Improving the OPTN Policy Development Process

GROUP 3: OPO: HIV Organ Policy Equity Act Planning

GROUP 3: Pancreas: Definition of Graft Failure

After review of the consent and discussion agenda, the Committee was provided the option to pull things from consent to discussion, and a Committee member wanted to bring the *VCA Implementation* proposal and the *VCA Data Submission* proposal to discussion. Another Committee member asked to bring the *Ops & Safety Develop Policy to Address Safety Concerns r/t Large Volume Waitlist Transfers* proposal off the consent agenda.

The Committee then voted to recommend that the remaining items on the consent agenda be released for public comment by a unanimous vote.

The Committee began its discussion of the remaining items on the discussion agenda, beginning with the MPSC proposal. The POC reviewed the comments from the survey on the QAPI MPSC proposal. One Committee member expressed concerned about what the motivation is for the MPSC to have completely separate QAPI requirements from CMS? What is the value added? Many POC members agreed with this, and expressed concerns that the QAPI requirements would be out of sync with CMS requirements. The PACE liaison for the MPSC commented that the MPSC is not able to use CMS requirements to take action when an OPTN member is out of compliance. Also, there are programs that are not CMS certified, so they would not be covered by the CMS requirements obviously. Another POC member repeated the concern that this is a duplicative effort and worried that a UNOS review would trigger a CMS investigation, thereby doubling the work of the program. The PACE liaison noted that the only monitoring that would occur would be in the context of an existing issue; there would be no routine monitoring of this by site surveyors.

After further discussion, the Committee voted on recommending that the MPSC's Quality Assurance & Process Improvement Initiatives proposal not go out for public comment, by a vote of 10 against and 4 wanting it to proceed to public comment. The POC offered the following comments about this proposal:

*CMS already has Quality Assurance & Process Improvement Initiatives requirements in place and this is duplicative of their requirements. Does not add value since CMS is already doing it and MPSC has other ways of looking at under-performing programs. However, staff explained that not all transplant programs are CMS certified and also the MPSC has no course of action based on a CMS review.*

The Committee then moved on to the Executive Committee's *Improving the OPTN Policy Development Process* proposal. A POC member communicated concern that there is no process for communicating to the membership emergency changes outlined in the proposal. Policy Director James Alcorn described the process and the POC member asked that this clarification be added to the background of the policy language. Committee members expressed the opinion that there needs to be more precise policy language about what exactly constitutes an emergency and what is considered a "regulatory" change. They requested that the background explanation in this proposal be clarified to include how the transplant community would be notified when there is an emergency policy/bylaws change and what is considered a regulatory change. The language that describes what is considered an emergency should be very limited and very clear. The Committee then voted unanimously (14-0) to recommend that this proposal go out for public comment.

The Committee then moved on to the OPO Committee's proposal *HIV Organ Policy Equity Act Planning*.

One comment said that there seems to be a contradiction in the description of this proposal: "enabling research" in the patients receiving an HIV+ organ versus "increasing availability of organs for candidates with HIV". These are different goals but both are stated in this proposal. The proposal should be clarified (remove this ambiguity) before going to public comment. One Committee member felt that the notion that this is "experimental" was important to include. The Committee also commented that the proposal has a very large cost for the benefit it will likely achieve. The Vice Chair of the OPO Committee reiterated that the proposal simply allows this to happen. Another Committee member expressed that he was disappointed that this is a huge, monumental programming effort to pull this off, and it will not have a lot of "bang for the buck." The Committee then voted unanimously (14-0) to recommend that this proposal go out for public comment.

The Committee then moved on to the Pancreas Committee's *Definition of Graft Failure* proposal. The Chair briefly talked about the proposal and asked that the POC recommend that the proposal go out for public comment. The Committee then voted unanimously (14-0) to recommend that this proposal go out for public comment.

The Committee then discussed the Ops & Safety Committee's proposal to *Develop Policy to Address Safety Concerns r/t Large Volume Waitlist Transfers*. This proposal should solve the problem by allowing these transferred patients to be put on inactive status so as to put less burden on recipient transplant programs. The Ops and Safety Vice Chair commented that this had been considered and the reasons for not doing this is articulated in the public comment proposal. No further objections were raised so the Committee made the recommendation that this goes out for public comment.

The Committee then discussed the two VCA proposals: *VCA Implementation* and *VCA Data Submission*. The POC received significant comments from the Living Donor Committee through their Vice Chair who serves on the POC. There was concern that there was not transparency about the inclusion of living donors in these policies. This policy language could permit living donor VCA donation at this time. The Living Donor wanted this to be resolved and especially outlined how this will affect living donation and what will be allowed. The POC Chair assured the Living Donor Committee member that their comments would be provided to the Executive Committee. Policy Director James Alcorn added that the background material would be amended for the proposals to better address this. The VCA Vice Chair provided education about the opportunities that living donors might provide for VCA transplantation. He said he understood the consternation about this, but that there is a need to be very careful about how we define living donor VCA. The Living Donor Vice Chair reiterated that they still felt strongly that there needs to be transparency in this and asked for some clarification in the background materials, even the statement that this does not apply to living donors. The Committee briefly discussed the Data Collection proposal, and then voted to recommend to the Executive Committee that these go out to public comment, although there are significant concerns about the failure to address living donation.

The POC Chair summarized the decisions made during the call and reiterated that the Executive Committee would be provided with these recommendations the POC voted on at its conference call the following Monday, September 15.

The meeting adjourned at 3:05 pm EST.

### **Upcoming Meetings**

- October 20-21, 2014, O'Hare Hilton, Chicago, IL
- November 21, 2014, 2-3 PM EST, Conference Call