

OPTN/UNOS Patient Affairs Committee
Meeting Minutes
July 17, 2018
Conference Call

Darnell M. Waun, MSN, RN, Chair
Garrett W. Erdle, MBA, Vice Chair

Introduction

The Patient Affairs Committee (PAC) met via Citrix GoToTraining teleconference on 07/17/2018 to discuss the following agenda items:

1. Overview of Constituent Council Meeting Structure
2. OPTN Final Rule¹ and NOTA² Education
3. Executive Committee Report

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

1. Overview of Constituent Council Meeting Structure

UNOS staff advised that for the next six months, the plan is to cover an education topic and a committee report during each monthly conference call. UNOS staff noted that an automatic check-in has been added to Basecamp and if committee members have a specific education request it can be emailed to the liaison or posted on Basecamp. UNOS staff also agreed to provide assistance with Basecamp if needed.

The Committee Chair welcomed the members and noted that his approach to the work of the PAC is based on two things:

1. All OPTN/UNOS policy decision impact patients either directly or indirectly. This means that the PAC has a powerful voice in the policy development process.
2. The diversity on the PAC is its strength and committee leadership is committed to channeling the collective voice of the patients and donor families in our activities.

2. OPTN Final Rule and NOTA Education

UNOS staff noted that Committee leadership has requested more education on OPTN policies and other related OPTN topics for PAC members. As a result, the Committee is engaged in a monthly learning series to ensure members are comfortable with these topics and how they interact with the work of the OPTN. UNOS staff provided an overview of NOTA which established the OPTN in 1984 to maintain a national organ matching registry and called for the network to be operated under federal contract by a private, non-profit organization. UNOS staff also noted that the Final Rule established the regulatory framework for the structure and operation of the OPTN. UNOS staff provided an overview of section 121.8 of the Final Rule because it addresses geography. This section outlines how allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5)."

¹ [OPTN Final Rule](#)

² [National Organ Transplant Act](#)

Summary of discussion:

One committee member commented that geography must be an important aspect of allocation policy since it is specifically addressed in the Final Rule. UNOS staff noted that all of our policies and bylaws need to be consistent with the Final Rule and NOTA. Historically, our policies have used DSA (or Regions) as the first level of distribution with a push in recent years to distribute organs more broadly.

3. Executive Committee Report

The Board of Directors' Vice-President for Patient/Donor Affairs provided an overview of the geographic organ distribution principles and their alignment with the Final Rule. She noted that geographic distribution is not the same as allocation. Finally, she noted that section 121.4 of the Final Rule allows "any interested individual or entity to submit critical comments related to the manner in which the OPTN is carrying out its duties" and outlines what actions the Secretary may take following review of the comments.

She provided an overview of the letter received from a law firm contesting the current and recently approved liver policies as being inconsistent with the Final Rule. She also provided information and a timeline for the additional letters that were sent in response to the initial letter.

The next steps to address this issue include:

- Liver Committee – propose replacements for DSA and region in liver policy which will require special public comment in October 2018 with approval by the Board of Directors in December 2018.
- Geography Committee – distribution models distributed for public comment in Fall 2018.
- Thoracic, Kidney-Pancreas, and VCA Committees – begin work to replace DSA and Region in time for January 2019 public comment.

UNOS staff noted that these projects are a high priority and will require certain committee projects to be placed on hold, particularly those that require SRTR modeling or data analysis.

Summary of discussion:

UNOS staff provided a brief overview of what a DSA is as well as the POC (Policy Oversight Committee) since they are common acronyms that will be referenced a lot in the coming months.

There were several questions raised by committee members including:

- What was the content of the "Piedmont letter" referenced in the timeline? UNOS staff noted that the letter was from a law firm in Atlanta, Georgia representing Piedmont Healthcare. This letter was critical of the letter from the New York law firm and outlined support for the policies developed by the Liver Committee.
- Can the PAC members get a copy of the OPTN letter to HRSA? UNOS staff agreed to distribute the letter to PAC members following the conference call.
- How does NOTA and the Final Rule impact the work of the PAC? UNOS staff noted that the committee members should become familiar with both laws in order to identify the provisions that are specific to candidates and patients. This will be important as the PAC works with the other committees during the policy development process.

- What authority does the Secretary have over the performance of organ procurement organizations? An OPO representative on the call noted that OPOs undergo an extensive audit process from various organizations including UNOS, CMS, and AOPO.
- How are DSAs and Regions not consistently applied in allocation? UNOS staff noted that DSAs and Regions have been consistently applied, however, because of the variation in size and location and other factors, it creates vulnerability when challenges are made to these “arbitrary boundaries” being used for organ distribution.
- Has the new liver policy been fully implemented? UNOS staff noted that both the National Review Board and liver allocation policies are currently being programmed. The programming will obviously need to be reevaluated as the new proposals are being developed so the necessary programming adjustments can be made based on the policies eventually approved by the Board of Directors in December 2018.
- Was the May 30, 2018 letter addressing the upcoming liver policy change or the current policy? UNOS staff noted that the letter addresses the reference to DSAs and Regions in both the current policy and newly approved policy.
- With the varying numbers of donor hospitals within each DSA, could there be different modeling made available? UNOS staff noted that there was data reviewed as part of the lung proposal that can be shared with the committee. It provides a snapshot of all the donor hospitals within certain units, such as a 250 nautical mile circle. UNOS staff also noted that in the three distribution frameworks being distributed for public comment in August 2018, there will be information about the proximity of the donor hospitals to where the candidates are located.
- How does new technology, such as perfusion centers, impact geography? UNOS staff noted that committees will need to consider kidney perfusion, independent perfusion services such as ex-vivo lung perfusion, as well as free standing OPO recovery centers in the development of future proposals.

UNOS staff reminded the PAC members that as these distribution proposals move forward it is important to think about the impact on patients. Additionally, if there are things that need to be clarified or explained for the patient population, it is important to provide that feedback to the sponsoring committees. A committee member noted that a lot of patients might not be aware of how many donor hospitals are in their region.

Upcoming Meeting

- August 21, 2018