OPTN/UNOS Executive Committee Meeting Minutes
03/19/2019

Introduction

The Executive Committee met via teleconference on 03/19/2019 to discuss the following agenda items:

1. Welcome
2. Critical Comments to HHS Regarding Liver Policy

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

1. Welcome

The Committee Chair thanked everyone for attending. The meeting today will mainly focus on obtaining feedback from the Committee on the letter the OPTN received from HRSA regarding critical comment from the 10 transplant centers with concerns about the process used in the December decision related to acuity circle.

2. Critical Comments to HHS Regarding Liver Policy

Staff summarized the letter received from HRSA. HRSA has asked the OPTN and SRTR for input on the response to arguments made in critical comment from a law firm on behalf of 10 transplant hospitals alleging that the new liver policy is inconsistent with the Final Rule. Instead, feedback at today's meeting will be used to make an outline that will be distributed to the members, and final approval will be done at next week's meeting.

The response from questions posed by HRSA will cover:

1. The Policy Development Process
    - Makeup of the Board and OPTN Committees
    - Public comment process and commented provided to Liver Committee
    - Lengthy discussions at the Board Meeting by professionals, important stakeholders, and Patient & Donor Affairs representatives
    - HRSA's December letter stating that the final policy was compliant with the Final Rule
2. Socioeconomic Inequalities
3. Impact on patient access to transplantation,
4. Further explanations of SRTR modeling as requested in the letter
5. Rationale for using Median MELD at transplant (MMaT) in the policy

<u>Summary of discussion</u>

The Committee's response their opportunity to provide formal feedback before HRSA responds to the critical comment letter from the law firm/10 transplant centers, as well as the various members of Congress. OPTN's input to the government will be public. A member suggested that the path that the lung policy took may be useful reference, and staff agreed to incorporate.

The letter includes an allegation that the Board is not qualified to make the decision it did. Staff clarified that it is more common for the Board to take a policy unamended, but there is sufficient evidence that the Board is qualified to make a different decision than a committee's decision. It is not normal practice for the Board to adopt something that a committee has not developed or considered. The response could make note of the fact that the Liver Committee was split.

A member asked if the OPTN has any plans for trying to get more cost data. Work is being done to purchase either CMS data or other payor data, and whether payor data set may be big enough to draw conclusions from. AOPO did a survey on cost, but surveys do not allow for a comprehensive set of results. Also, some work on overall cost revealed reduced cost in caring for the most critical patient was greater than the likely increased cost in transportation, but that is not evenly distributed.

If the law firm does not get the answer they desire, their stated intention is to sue. Members noted that there no centers from Kentucky or South Carolina in the letter, though these states are used as part of their argument against the liver allocation policy. Another member asked that if modeling suggested certain areas have a relative advantage in access and the new policy will bring those areas closer to national average, what is that advantage and should this chance for equitability be front and center? That is indeed the entire point of the policy, but it doesn't change candidates with lowest MELD scores to highest MELD scores. It just moves everyone closer to the middle. The draft could explain this more clearly. The Chair encourages shining a light on this point.

Several comments talk about access to the waitlist and access to care, but this is not what's being addressed. Allocation policy cannot improve access to the waitlist. CMS might better address broader access to transplantation services.

Next steps

- Staff will distribute the draft of the response to the Committee members based on the feedback received today.
- Back and forth discussions regarding any specific comments can be made continuously throughout the week via email or by phone.
- If there are any comments that need clarification or cannot be resolved, they can be discussed at the next meeting.
- As of now, implementation date for liver will still be April 30th.
- The Executive Committee will reconvene on 3/26/2019.