**OPTN Transplant Administrator Committee**
**Financial Impact Advisory Workgroup**
**Meeting Summary**
**October 28, 2021**
**Conference Call**

**Nancy Metzler, Chair**
**Susan Zylicz, Vice Chair**

## Introduction

The Transplant Administrator Committee's Financial Impact Advisory Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 10/28/2021 to discuss the potential fiscal impact on transplant programs, organ procurement organizations (OPO), and histocompatibility labs for the following public comment proposals:

1. Redefining Provisional Yes and the Approach to Organ Offers
2. Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing
3. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation
4. Establish OPTN Requirements for Race-Neutral eGFR Calculations
5. Ongoing Review of National Liver Review Board Policy and Guidance
6. Improving the MELD Calculation and Reducing Pediatric Liver Waiting List Mortality

The Workgroup met to discuss the concluding batch of proposals that will be going out for the winter/spring public comment cycle of 2022. This was the last Workgroup meeting for the 2022 public comment cycle.

The following is a summary of the proposals and the Workgroup's discussions.

## 1. Redefining Provisional Yes and the Approach to Organ Offers

The Workgroup reviewed the Operations and Safety Committee's proposal to address inefficiencies in organ match runs. Transplant programs have noted difficulty in evaluating organ offers with provisional yes' earlier in the match run, as the timeframe for when the offer will become primary is inconsistent. This is an increasing issue as more organs are being shared, consequently increasing organ offers. The proposal seeks to elucidate the information available to programs at the time of the offer, the criteria for timing out programs that have exceeded their evaluation time, and to increase the transparency of match runs. Primarily, the Operations and Safety Committee hopes to address these as educational issues.

The Workgroup believed there was an opportunity to save money with the implementation of this proposal, as it should ultimately increase organ allocation efficiency through match transparency. It was also hypothesized that, as this is an educational opportunity, programs would be able to operate more efficiently with a better understanding of the tools at their disposal during allocation.

## 2. Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing

The Workgroup reviewed the Disease Transmission Advisory Committee (DTAC) and Pediatric Committee's proposal to evaluate testing requirements for pediatric candidates prior to transplant for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV). The proposal

addresses the risk of over-drawing blood volume for the testing of HIV, HBV, and HCV when done on hospital admission and immediately prior to transplant in infants and small children. The proposed solution is to change the requirements for candidates ten years or younger to require testing upon hospital admission, but to broaden the window for immediate pre-transplant testing.

Based on this proposed change, there is no anticipated financial impact for this proposal. The testing will still be performed, but with a larger window of time to allow for greater pediatric patient safety. A DTAC member noted that, given the larger window for testing, this could potentially reduce the number of repeat tests having to be done.

**3. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation**

The Workgroup discussed the proposal from the ad-hoc Multi-Organ Transplantation Committee (MOT), which addresses inconsistencies in multi-organ allocation surrounding safety net heart-kidneys and lung-kidneys. The proposal will establish eligibility criteria for these safety net multi-organ combinations and propose requirements to mirror the eligibility criteria for simultaneous liver-kidney (SLK) allocation. These changes will help ensure clinical justification for multi-organ candidates, while not inappropriately prioritizing these candidates over kidney alone candidates.

As there will be changes to waitlist fields, as well as candidate registration forms, there is expected to be a minimal financial impact to OPOs and transplant centers. Included in this estimate is the education that will be required if the proposed changes come into effect. With the data available from the proposal, there are no areas where cost savings are expected.

A Workgroup member did inquire as to how the proposed changes would interact with Continuous Distribution, and a member from the MOT replied that the two proposed policies would roll out in tandem. The MOT member noted that they have taken into consideration that they were not developing a system that would need to be remade in the context of Continuous Distribution.

**4. Establish OPTN Requirements for Race-Neutral eGFR Calculations**

The Minority Affairs Committee and Kidney Committee jointly produced a proposal on establishing uniform requirements for calculating estimated Glomerular Filtration rate (eGFR). Specifically, the two Committees propose a transition to a more equitable calculation that would no longer automatically assign a higher filtration value for black patients, which currently negatively impacts their ability to be transplanted.

While OPOs and histocompatibility labs do not foresee any financial impact from this proposal, transplant programs could be impacted from a change in hospital listing practices, as the number of candidates who are able to be listed could increase. Additionally, there could be contractual agreements in place that would be impacted if programs are outsourcing their eGFR testing.

One Workgroup member wondered whether there would need to be any software changes as a reaction to this and whether that would be a significant financial burden. The FIG presenter replied that they had already worked with a transplant program already on this transition ahead of the requirement change and had found it to be very similar to be not very significant. A second member also asked why a singular formula wasn't being recommended, especially with the obvious benefit of being able to highlight that formula with a calculator on UNet$^{SM}$. The representative for the proposal responded that, during development of the proposal, a number of Committee members felt strongly that it would not be in the OPTN's best interest to mandate on type, as it is a formula that will continue to be improved and upgraded over time. Additionally, while it may seem equitable to define one formula as the race-neutral formula used by the OTPN, the OPTN Committees do not want to legislate program-level practices.

**5. Ongoing Review of National Liver Review Board Policy and Guidance**

The Workgroup listened to proposed guidance submitted by the Liver and Intestine Committee on creating consistent review of exceptions by the National Liver Review Board (NLRB). Every six to eight months, the NLRB will review updates to guidance documents that help determine their exception approval or refusals. The guidance was submitted following the NLRB's request for feedback for improvement.

The guidance documents proposed will update the reference material on ischemic cholangiopathy and hepatocellular carcinoma (HCC). The updates will improve the NLRB's uniformity in decision making, as well as equity in exceptions.

The Workgroup did not feel that there would be any financial impact as the proposal seeks only to update guidance documents.

**6. Improving the MELD Calculation and Reducing Pediatric Liver Waiting List Mortality**

Finally, the Workgroup reviewed the Liver and Intestine Committee's proposal to update the model for end-stage liver disease again, following their 2016 update, to better predict the likelihood of waitlist mortality. Currently, women are disproportionately disadvantaged on the list due to size, prevalence HCC, and statistically lower creatinine levels due to lower muscle mass. In addition, the Committee will update the model for pediatric end-stage liver disease (PELD), which has not been updated in approximately 20 years. Research has shown that PELD score's ability to predict the risk of waitlist mortality has decreased over time.

The Committee is proposing to adding a sex variable, which adds additional points if the candidate is female. The Committee will also update the model for PELD, which will not add any elements, but rather change values to better predict waitlist mortality.

There is minimal expected financial impact for any party beyond baseline education costs.

A Workgroup member noted that there may actually be financial savings because of this policy, if patient outcomes are improved by it. Additionally, one side effect of the update to PELD would be an increase in patient volume, which would also have a positive financial impact. Following no additional comments, the Workgroup members were requested to fill out the follow up survey, and the meeting concluded.

**Upcoming Meeting**

- **Spring 2022**

**Attendance**

- **Committee Members**
  - Nancy Metzler
  - Susan Zylicz
- **HRSA Representatives**
  - First Name Last Name
- **SRTR Staff**
  - First Name Last Name
- **UNOS Staff**
  - Rebecca Brookman
  - Matthew Cafarella
  - Abby Fox
  - Isaac Hager
  - Kristina Hogan
  - Courtney Jett
  - Lindsay Larkin
  - Eric Messick
  - Laura Schmitt
  - Susan Tlusty
  - Joann White
- **Other Attendees**
  - Debbie McRann