

**OPTN Transplant Administrator Committee
Fiscal Impact Advisory Workgroup
Meeting Summary
May 11, 2022
Conference Call**

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

Introduction

The Fiscal Impact Advisory Workgroup of the Transplant Administrator Committee met via Citrix GoToMeeting teleconference on 05/11/2022 to discuss the potential fiscal impact of the following public comment proposals on the OPTN histocompatibility laboratories (lab), organ procurement organizations (OPO), and transplant programs:

1. Apply Transplant Program Notification Requirements for VCA Program Inactivation (Vascularized Composite Allograft Committee)
2. Modify Candidate Waiting Time Dates Affected by Race-Based eGFR Calculations (Minority Affairs and Kidney Committees)

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

1. Apply Transplant Program Notification Requirements for VCA Program Inactivation

The Workgroup reviewed the proposal from the Vascularized Composite Allograft (VCA) Committee, Apply Transplant Program Notification Requirements for VCA Program Inactivation. Currently, OPTN bylaws govern the process for transplant programs to notify their candidates about program inactivity, short-term inactive status, and long-term inactive status. However, VCA transplant programs were originally brought under the OPTN's purview, they exempted from the requirements. The proposed changes would apply the inactivity requirements to VCA programs as well. It was mentioned that the proposal only requires VCA programs to notify patient; the proposal does not impact the criteria for program inactivation.

In addition, the proposal would amend the OPTN bylaws to update the reference to eight VCA program types to ten VCA program types. The clarification would reflect the December 2021 decision by the OPTN Board of Directors' approving splitting the "genitourinary organ" VCA type into three VCA types: uterus, external male genitalia, and other genitourinary organs.

A Workgroup member stated that the fiscal impact associated with the proposal falls on the VCA transplant programs and the efforts around notifying their potential waitlisted patients of program status changes. Other organ-specific transplant programs are unlikely to be experience any fiscal impact if the proposal is approved. There was no expected fiscal impact to OPOs resulting from the proposed changes.

2. Modify Candidate Waiting Time Dates Affected by Race-Based eGFR Calculations

The Workgroup reviewed the joint proposal of the OPTN Minority Affairs and Kidney Committee's that would modify kidney candidate waiting time dates for those candidates affected by transplant programs' use of race-based eGFR calculations. The proposal would address the modifications of waiting time for Black Race kidney candidates who are impacted by calculations of eGFR that consider race. Transplant programs would be given the opportunity to modify the waiting time of impacted candidate who were already listed for transplant at the time of implementation as to not disadvantage the group based upon the time that they were initially listed. Programs would be allowed to backdate a candidate's waiting time to an earlier qualifying date for Black kidney candidates regardless of the candidate's listing date. The proposal follows the Minority Affairs and Kidney Committees' work that is scheduled for review by the OPTN Board of Directors in June 2022 that would prohibit the use of eGFR calculations that include a race-based variable. It has been determined that race-based eGFR calculations often overestimate kidney function, and thus give the impression that a candidate's kidney(s) are functioning better than they actually are. As part of the earlier public comment proposal, the committees asked for community feedback as to whether the OPTN should consider developing a pathway for transplant centers to modify waiting time for kidney candidates who could begun accruing waiting time at an earlier date if the race neutral eGFR calculation was used? As a result of community feedback to the question in the earlier proposal, the Minority Affairs and Kidney Committees are partnering again to develop a proposal to address how additional waiting could best be provided.

A consideration of the proposal FIG is reviewing can involve either an automated or manually processed waiting time modification for programs to submit to the OPTN. The two committees will also address eligibility requirements, including the required documentation to determine candidate eligibility. The committees are proposing that the solution should have a narrow scope, specifically focused on listed candidates. Currently listed candidates would have their waiting times modified within a limited timeframe, and the timeframe has yet to be determined. As mentioned, the solution should include clear and specific documentation for modification.

As a result, transplant programs would need to assess their specific kidney waiting lists and identify those candidates based on the eligibility that defined. The programs would then need to create their own workplan on how they will accomplish identify the candidates. Additionally, programs will need to ensure that they are securing and including in the medical record the specific documentation that would be needed in order to support the request waiting time modification, and how they perform the activities within the timeframe established for submitting such requests

A Workgroup member affiliated with a transplant program stated that the proposal will mean a small amount of work for programs depending on the number of potential candidates they have, but the work being proposed is very important, and should be performed.

A Workgroup member asked if the race-neutral eGFR calculations have been validated in clinical practice? The Kidney Committee member stated that there are several race-neutral calculations available for use. In fact, the most recently updated version of the Chronic Renal Insufficiency Cohort (CRIC) with creatinine equation does not include race, and has found to be more accurate than the inclusion of race was. The Workgroup member also asked whether the Minority Affairs and Kidney committees are recommending that transplant programs use a specific race-neutral calculation or make their own decisions? The Kidney Committee members stated that the recommendation is for the transplant programs to decide which race-neutral calculation to use. Given the different equations already in use, and the transplant programs' reasons for using them, it was determined that the best option is to leave the decision to the transplant programs rather than for the OPTN to try to develop consensus around a single equation.

Part of the public feedback received regarding the Minority Affairs and Kidney Committees' proposal, *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, asked how candidates who lost waiting time as a result of the use of a race-based eGFR equation might be able to reclaim that time. The *Establish* proposal is being presented to the OPTN Board of Directors in June 2022. When the Board considers the proposal, the Minority Affairs and Kidney Committees also want to be able to present a plan for how the issue of potential lost waiting time might be addressed.

A Workgroup member asked whether the existing process for modifying wait time established in OPTN policy is sufficient to remedy the situation? It was discussed that the current policy is used to remedy circumstances when a transplant program erred in listing a candidate. In the case of restoring lost wait time for candidates impacted by the use of race-based calculations, transplant programs were operating in accordance with approved policy, and therefore, no errors were committed. It was also mentioned that the timeframe will be limited for claiming lost waiting time as due to the use of race-based eGFR calculations, so that this process falls somewhat outside the waiting time modification process established in policy already.

Upcoming Meeting(s)

- To be determined based on feedback received during August-September 2022 public comment cycle

Attendance

- **Fiscal Impact Advisory Workgroup Members**
 - Amber Carriker
 - Kevin Koomalsingh
 - Debbi McRann
 - Stacy Sexton
 - Laura Stillion
 - Scott Wansley
- **HRSA Representatives**
 - Vanessa Arriola
 - Raelene Skerda
- **SRTR Staff**
 - None
- **UNOS Staff**
 - Kristina Hogan
 - Krissy Laurie
 - Eric Messick
 - Kelley Poff
- **Other Attendees**
 - Sandra Amaral, OPTN Vascularized Composite Allograft Transplantation Committee
 - Martha Pavlakis, OPTN Kidney Committee