

Meeting Summary

OPTN Minority Affairs Committee
Meeting Summary
March 31, 2025
Conference Call

Alejandro Diez, Chair Oscar Serrano, Vice Chair

Introduction

The OPTN Minority Affairs Committee (the Committee) met via WebEx teleconference on 03/31/2025 to discuss the following agenda items:

- 1. Monitor Ongoing eGFR Modification Policy Requirements
- 2. Kidney Donor Profile Index (KDPI) Creatinine Discussion

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

1. Monitor Ongoing eGFR Modification Policy Requirements

The Committee reviewed the public comment analysis, resolved open items, and voted the *Monitor Ongoing eGFR Modification Policy Requirements* proposal forward for consideration by the OPTN Board of Directors.

Summary of discussion:

Decision #1: The Committee recommended retention of the retroactive notification requirement as proposed in public comment. The Committee recommended a one- year timeframe for transplant programs to complete this requirement.

Decision #2: The Committee recommended that transplant programs must notify candidates within 10 business days following the program's receipt of modification outcome from the OPTN.

Decision #3: The Committee unanimously voted the *Monitor Ongoing eGFR Modification Policy Requirements* proposal forward for consideration by the OPTN Board of Directors.

Vote: Support- 10, Oppose- 0, Abstain- 0

Overall, public comments demonstrated broad support for the intent and clarity of the proposed protocols and documentation standards. Many stakeholders emphasized that these measures are important for advancing equity, improving transparency, and promoting accountability across transplant centers. Commenters also appreciated the proposal's flexibility, allowing programs to determine how best to implement and document these requirements in a way that fits their programs' policies and workflows.

The Committee discussed and resolved two open items: 1) determine if proposed retrospective notification requirements should be retained or removed and 2) decide whether to set a timeframe for notifying candidates after the program receives modification submission outcome.

Retroactive notification requirement

The proposal includes a requirement for transplant programs to retrospectively notify all kidney candidates registered on or after January 4, 2024, of their eligibility and outcome¹ related to *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations* eGFR. Public comment reflected a divided perspective within the transplant community regarding this part of the proposal.² Several stakeholder committees, organizations, and individual commenters expressed opposition to the retroactive notification requirement, advocating instead for a prospective approach. These respondents emphasized that implementing retrospective notifications would place significant strain on program resources, disrupt day-to-day operations and competing priorities, and could result in duplicative efforts if candidates had already been notified. In contrast, those who supported the proposed retrospective requirement cited equity and transparency as foundational principles. Supportive commenters highlighted the importance of ensuring that all transplant candidates are informed of their eGFR modification status in a consistent and fair manner, regardless of when their registration occurred.

The MAC thoughtfully considered retention or removal of the proposed retrospective notification requirements. While the MAC acknowledged the additional workload the retrospective component of this policy may place on transplant programs, they concluded that ensuring kidney transplant candidates fully understand how *OPTN Policy 3.7.D* impacts them outweighs the associated administrative burden. The MAC determined that retaining the retrospective notification requirement as the recommended course of action, as it prioritizes the patient and reinforces trust in the transplant process. After determining they would recommend the retrospective notification requirement be retained as proposed in public comment, the MAC discussed an appropriate timeframe for its completion. Timeframes of six months, nine months, and one year were considered. The Committee emphasized that the timeframe should be uniform across all transplant programs, regardless of size, and should reflect the time needed for programs with the highest volume of affected candidates to comply. Additionally, the MAC expressed support for allowing more time to meet the requirement, acknowledging the mixed feedback received during the public comment period. For these reasons, the MAC determined it would recommend that transplant programs be given one year from the policy's implementation date to complete the retrospective notification requirements.

<u>Timeframe for outcome notification after program receives outcome</u>

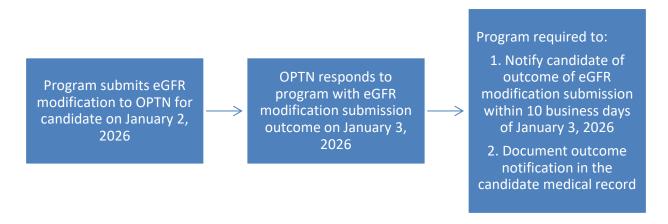
During public comment, the Committee received a recommendation from the OPTN Membership and professional Standards Committee (MPSC) to establish a timeframe for notifying candidates following a program's receipt of the eGFR modification submission outcome from the OPTN. Both committees agreed that such a requirement would enhance system transparency and enable more specific compliance monitoring. While the MPSC recommended a 30-day notification timeframe, the MAC determined that a 10-day notification timeframe would be more appropriate, aligning with existing OPTN policies such as *Policy 3.5: Patient Notification* and *Policy 3.6.C: Individual Waiting Time Transfers*.

¹ For candidates that had an eGFR waiting tome modification submitted

² OPTN Public Comment. Monitor Ongoing eGFR Modification Policy Requirements, OPTN Minority Affairs Committee, January 2025. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/monitor-ongoing-egfr-modification-policy-requirements/ (accessed April 8, 2025).

Figure 1 illustrates an example of the proposed outcome notification process. The 10-day timeframe is calculated from the date the OPTN communicates the modification outcome to the transplant program. This requirement would be applied to candidates registered on or after the policy's implementation.

Figure 1. Outcome notification timeframe example



After resolving these open items, the Committee unanimously voted the *Monitor Ongoing eGFR Modification Policy Requirements* proposal forward for consideration by the OPTN Board of Directors. Vote: Support- 10, Oppose- 0, Abstain- 0

Next steps:

The *Monitor Ongoing eGFR Modification Policy Requirements* proposal will be presented for consideration by the OPTN Board of Directors in June 2025.

2. Kidney Donor Profile Index (KDPI) Creatinine Discussion

An SRTR representative presented the impact of creatinine modeling changes on KDPI calculations following the removal of race and HCV variables from the KDRI (Kidney Donor Risk Index)/KDPI model.

Summary of discussion:

No decisions were made.

The way serum creatinine is modeled in the KDPI equation creates a change in slope at a creatinine level of 1.5 mg/dL. In the original 2009 analysis, the slope above 1.5 was positive, meaning that higher creatinine levels correlated with higher graft failure risk. However, in the updated model, the slope beyond 1.5 mg/dL has become slightly negative, resulting in higher creatinine values being associated with a marginally lower KDPI. The presenter explained that this shift in slope is not a result of removing race or HCV from KDPI but appears to be influenced by differences in donor data cohorts and updates in death and graft failure reporting. The presenter stated that the slope for creatinine above 1.5 mg/dL in the model is not statistically significantly different from zero. If the community thinks the negative slope for creatinine above 1.5 mg/dL does not make clinical sense, one way to address this would be to cap creatinine at 1.5 mg/dL in the KDPI model, effectively changing the slope for creatinine above 1.5 mg/dL to zero.

Committee members expressed surprise at the minimal effect that high creatinine values have on KDPI. Some noted the inherent variability in creatinine values based on donor management and timing, reinforcing the importance of specifying the creatinine timepoint used to calculate KDPI. While acknowledging the statistical soundness of the current model, the Committee emphasized the need for transparency in how the model works. Ultimately, the Committee agreed that the issue should be referred to the OPTN Kidney Committee for further review.

Next steps:

The Committee will revisit the topic after additional feedback is collected from relevant stakeholders.

Upcoming Meetings

• May 19, 2025, 3-4pm ET

Attendance

Committee Members

- o Alejandro Diez
- o Adrian Lawrence
- o Hilda Fernandez
- o John Bayton
- Steven Averhart
- Anthony Panos
- o April Stempien-Otero
- o Tony Urey
- o Donna Dennis
- o Catherine Vascik

SRTR Staff

- Warren McKinney
- o Jon Miller
- o Bryn Thompson
- o Monica Colvin

UNOS Staff

- Houlder Hudgins
- o Susan Tlusty
- o Kelley Poff
- o Sarah Booker
- o Matt Cafarella
- o Laura Schmitt
- o Alex Carmack

Other Attendees

o Brittany Clayborne