Background

In winter 2022, the Minority Affairs and Kidney Transplantation Committees co-sponsored the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* public comment proposal. This proposal's purpose was to prospectively prohibit the use of eGFR calculations that include a race-based variable in OPTN policy. The proposal received widespread community support and was passed by the OPTN Board of Directors on June 27, 2022, and implemented on July 27, 2022.

Then, Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations was passed by the OPTN Board of Directors on December 5, 2022, and implemented on Jan. 5, 2023. The policy requires transplant programs to assess their respective waiting lists and submit eGFR waiting time modifications for candidates disadvantaged by use of a race variable in their eGFR calculation.

On March 15, 2023, the OPTN hosted an eGFR modification implementation webinar. The OPTN received questions regarding the policy, which have been organized into the following themes:

Scope

<u>Narrow scope:</u> The scope of this policy is designed to address a potential inequity related to transplant program waiting list practices for Black or African American patients who were impacted by race-based eGFR calculations. The purpose of this policy is to restore waiting time to Black or African American candidates who may have been potentially impacted by a race-inclusive eGFR.

- The scope of this policy does not include:
 - Addressing late referral to the waiting list for all candidates
 - Addressing overall access to the waiting list for all candidates
 - Addressing overall program practices related to "when" it is appropriate to list a candidate
 - Addressing larger healthcare inefficiencies in the United States healthcare system

Eligibility

- <u>Candidates who may be eligible:</u> Only candidates who are registered on the kidney waiting
 list as Black or African American are potentially eligible for this eGFR waiting time
 modification because they are the only group of candidates who might have been
 disadvantaged by use of a race factor in the calculation of their eGFR.
- Span 20: The transplant program must provide documentation demonstrating that with a race-inclusive calculation, the candidate's eGFR was over 20 mL/min, but with a race-

neutral calculation, it would have been 20 mL/min or less. Span 20 means that the race-based value is greater than 20, and with a race-neutral calculation, the GFR is 20 or less.

- This criteria for eligibility was established to directly link the use of a race-inclusive eGFR calculation to a candidate's late access to the waiting list. A candidate of any race could experience late access to the waiting list due to late referral, so this requirement aims to focus specifically on those disadvantaged by their transplant program's use of a race-based eGFR calculation. If this documentation can be provided, the candidate will be considered eligible for backdating prior to their original qualifying date.
- Other criteria: This policy does not take medical suitability, or other such criteria into consideration. If the transplant program can provide the required supporting documentation, the candidate is considered eligible for a waiting time modification.

Seeking Supporting Documentation

- Obtaining records: Programs are expected to take the necessary steps to modify waiting times for kidney candidates disadvantaged by use of a race-inclusive eGFR calculation. To do this, programs are expected to seek documentation by:
 - 1. Reviewing their own records
 - 2. Contacting referring nephrologists for additional information
 - 3. Contacting candidates, who may have additional information
- No limits on how much waiting time can be restored: There is no limit to how far back a program may look or how much waiting time a Black kidney candidate can have restored, so long as the required supporting documentation is provided.
- Two options for required supporting documentation:
 - Documentation of the candidate's eGFR value for Black and non-Black candidates: This documentation is reliable and widely available from labs, such as Quest Diagnostics or LabCorp.
 - 2. Documentation showing both the estimation of GFR with a race- inclusive calculation and a re-estimation of GFR with race-neutral calculation: Not every transplant program will have access to the documentation referenced in option 1.

Programs without access to larger labs may provide the following two documents to support eGFR waiting time modifications:

- a. A lab report showing estimation of a candidate's GFR with a race-inclusive calculation, including the date and time of estimation.
- b. Evidence of re-estimation of the candidate's GFR with any race-neutral eGFR calculation demonstrating a qualifying value.

Notifying candidates & submitting modifications

- <u>Use of race- neutral eGFR calculators:</u> This policy does not recommend use of any specific race- neutral eGFR calculator. Any eGFR calculator may be used, so long as it does not include a race variable.
- <u>Changing a candidate's race:</u> If a kidney candidate's race has been misrepresented, the transplant hospital should correct this candidate's race in the OPTN Computer system.
 - OPTN policy does not speak to any documentation required to change a candidate's race in the OPTN computer system.
 - If the candidate's race is now Black or African- American, they must be assessed for a waiting time modification.
 - Eligibility will be determined by past use of a race-inclusive eGFR and supporting documentation outlined in the policy. If a race-inclusive eGFR calculation was never used, the candidate will not qualify.
- <u>Electronic signatures:</u> If a program is using an E- signature to submit the Waiting Time Modification Form, it must include a time stamp to be accepted by the OPTN.
- <u>Submission acceptance:</u> Programs will only be notified by the OPTN if an eGFR waiting time modification submission was not approved. If your program is not contacted by the OPTN, your modification applications have been approved.
- <u>Records management:</u> While not required by policy, the OPTN recommends that transplant programs keep documentation of candidate notification and modification submissions for their own records.

Compliance

- <u>Timeline:</u> OPTN policy does not require programs to review/assess their list at specific time points. OPTN policy requires programs to fulfill all requirements of the policy by Jan. 3, 2024, and are encouraged to review their list expeditiously.
- Attestation submission: Programs may submit their attestation before Jan. 3, 2024, by selecting a point in time on the waiting list, fulfilling policy requirements for that group of candidates (assessment, modification submission, and notifications), and submitting their attestation.
 - Programs are required to continue to meet candidate notification and modification submission requirements through Jan. 3, 2024, regardless of when their attestation documentation is submitted to the OPTN.
- <u>Continuing requirements:</u> Even after Jan. 3, 2024, programs must continue to notify new candidates (notification 1) of the requirements of this policy.
- Evaluation for compliance: The OPTN will evaluate program compliance based upon submission of attestation documentation by Jan. 3, 2024

eGFR Resources

- The webinar is available in video format on the OPTN website. In addition, the OPTN website contains a web toolkit for additional information about this policy change including FAQs, background information, and education details.
- All of these resources can be found here.