

Briefing to the OPTN Board of Directors on

Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Filtration Rate (eGFR) Calculations

OPTN Minority Affairs and Kidney Transplantation Committees

*Prepared by: Kelley Poff
UNOS Policy and Community Relations Department*

Contents

Executive Summary	1
Purpose	2
Background	2
Proposal for Board Consideration	3
Overall Sentiment from Public Comment	15
Compliance Analysis	18
Implementation Considerations	20
Post-implementation Monitoring	21
Conclusion	22
Policy Language	23

Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Filtration Rate (eGFR) Calculations

<i>Affected Policies:</i>	<i>3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations</i>
<i>Sponsoring Committee:</i>	<i>Minority Affairs and Kidney Transplantation</i>
<i>Public Comment Period:</i>	<i>August 3, 2022-September 28, 2022</i>
<i>Board of Directors Meeting:</i>	<i>December 5, 2022</i>

Executive Summary

In winter 2022, the Committees co-sponsored the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* public comment proposal.¹ 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.

The OPTN Minority Affairs and Kidney Transplantation Committees submitted a follow-on proposal to provide a pathway for waiting time modifications for Black kidney candidates that are registered on the kidney transplant waiting list who have been affected by race-inclusive eGFR calculations. This proposed pathway provides programs a 365 day timeframe to review their waiting lists and request eGFR waiting time modifications for registered Black kidney candidates impacted by race-inclusive eGFR calculations. The paper summarizes the Committees' original recommendations and adjustments to those recommendations based on community input and additional discussion.

¹OPTN Public Comment. *Establish OPTN Requirement for Race- Neutral eGFR Calculations*, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022 https://optn.transplant.hrsa.gov/media/f2qpujia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed June 9, 2022)

Purpose

This proposal's purpose is to provide a pathway for Black kidney candidates who have been affected by race-inclusive eGFR calculation to obtain waiting time they would have otherwise earned had a race-neutral GFR calculation been used. When the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* policy was implemented, requirements for eGFR race-neutrality were applied prospectively. This means that after the policy's implementation date, transplant programs were required to use race-neutral eGFR calculations for all purposes of the OPTN, including initiation of waiting time accrual for kidney transplantation candidates. Current OPTN kidney policy states that GFR qualifying waiting time begins on or after the candidate's registration date.² This proposed pathway would require transplant programs to assess their respective waiting lists and submit eGFR waiting time modifications for affected candidates.

Background

The eGFR formula is a tool used to estimate the rate at which the kidneys remove waste products from the blood and helps determine the severity of a patient's kidney disease; it estimates how well the kidneys function.³ The average eGFR declines with age, but for adults ages 20-59 a normal eGFR is greater than 90 milliliter/minute (mL/min). An eGFR value less than 60 mL/min for more than three months indicates moderate to severe chronic kidney disease (CKD).⁴ The most severe stage of CKD is stage five which is defined by an eGFR value less than 15 (mL/min). Patients with stage five CKD eventually need regular dialysis or a kidney transplant to survive.⁵

GFR values are used as qualifying measures throughout OPTN policy. *Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older* requires one of the following to initiate kidney candidate waiting time accrual:⁶

1. The candidate's registration date with a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min.
2. The date after registration that a candidate's GFR or measured or estimated CrCl becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

Although these criteria are used for initiation of waiting time, they are not required for kidney candidate registration. A transplant program may register a kidney transplant candidate at any time, but the candidate will not accrue waiting time until one of the criteria listed in *Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older* is met.⁷ Waiting time plays a significant role in the prioritization of kidney offers. Generally, the earlier a candidate qualifies to accrue waiting time, the sooner they will receive access to a transplant absent other qualifying criteria.⁸

² OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

³ National Kidney Foundation. (2021). *Estimated Glomerular Filtration Rate (eGFR)*. National Kidney Foundation, Inc. <https://www.kidney.org/atoz/content/gfr>

⁴ Ibid.

⁵ Ibid.

⁶ OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

⁷ Ibid.

⁸ OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

During the winter 2022 public comment period, the Committees asked the community for feedback on if and how the OPTN should consider developing a pathway for transplant centers to modify waiting time for Black kidney candidates who could have begun accruing waiting time at an earlier date if a race-neutral calculation had been used to estimate their GFR.⁹ Community responses indicated interest in the concept, but did not provide further input on how eGFR waiting time modifications should be operationalized.¹⁰ The Reassess Race in eGFR Calculations Workgroup (the Workgroup), made up of members of the OPTN Minority Affairs and Kidney Transplantation Committees along with subject matter experts and patient representatives, reconvened to consider this complex issue and propose an equity-driven solution.¹¹

Proposal for Board Consideration

The OPTN Minority Affairs and Kidney Transplantation Committees propose a pathway for waiting time modifications for Black kidney candidates that are registered on the kidney transplant waiting list who have been affected by race-inclusive eGFR calculations by updating policy to require transplant programs to submit modifications to these candidates' waiting time. Under this proposal, candidates with approved eGFR waiting time modifications would see their waiting time backdated, unlimited by registration date. This portion of the paper outlines the Committees' original recommendations regarding scope, timeframe, and supporting documentation, as well as adjustments to those recommendations based on community input from public comment and subsequent discussions.

Post public comment discussion

Mandate modifications

During public comment it was proposed that programs' assessment of their respective waiting lists and submission of eGFR waiting time modifications on behalf of their Black kidney candidates would be optional. This solution was originally proposed as a voluntary opportunity because initially, the Workgroup thought requiring transplant programs to assess their waiting lists and submit modifications for potentially impacted candidates could be seen as an extensive mandate. The Workgroup believed this requirement would be opposed during public comment due to administrative burden, especially by large programs with long waiting lists. However, public comment feedback expressed overwhelming support for the proposed voluntary submission of eGFR modifications to become a requirement of all transplant programs. Supporting sentiment referenced ensuring more equity to all affected candidates, not just candidates registered at programs that voluntarily participate. Based on the community's widespread support and ongoing Committee discussions regarding the importance of candidate equity in access to transplant, by ensuring that every candidate who may qualify be evaluated, the Committees propose that each kidney transplant program be required to assess their kidney waiting lists and submit eGFR waiting time modifications for candidates whose waiting time may have potentially been impacted by a race-inclusive eGFR calculation.

⁹ OPTN Public Comment. *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022 https://optn.transplant.hrsa.gov/media/f2qpujia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed June 24, 2022)

¹⁰ OPTN Briefing to the Board of Directors. *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, OPTN Minority Affairs and Kidney Transplantation Committees, June 2022 https://optn.transplant.hrsa.gov/media/amsddvga/mac_establish-race-neutral-egfr-calculations_bp.pdf (accessed June 24, 2022)

¹¹ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, May 3, 2022. Available at https://optn.transplant.hrsa.gov/media/ldkpc3l/20200503_mac_ki_egfrwmods_summary.pdf

On October 17, 2022 the OPTN Minority Affairs Committee voted to support mandating eGFR waiting time modifications.¹² The OPTN Kidney Transplantation Committee also voted in support on November 7, 2022.

Monitoring

After the Committees determined waiting list review and subsequent eGFR modifications should be mandatory for transplant programs, they began to discuss if and how transplant programs should be monitored for compliance with this requirement. The Committees agreed that if programs are obligated to assess their kidney waiting lists and submit eGFR waiting time modifications for affected candidates, there should also be a mechanism for holding programs accountable for compliance. The Committees discussed several monitoring options with varying levels of OPTN oversight. The first option, with the least amount of OPTN oversight, would only require transplant programs to maintain their own documentation. The second option, with more OPTN oversight, would require transplant programs to submit documentation attesting to the completion of their waiting list review and submission of eGFR waiting time modifications for affected candidates. The third option, with the most OPTN oversight would involve requiring the submission of additional data to the OPTN, to include a full list of Black kidney candidates determined to be eligible or not eligible by the program.

Initially, when discussed by the Workgroup, members favored the third option with the most OPTN oversight. However, because this monitoring option would involve the collection of data and data collection was not included in the original proposal, the Committees found the third option to be outside of logical outgrowth of this project.¹³ Any new OPTN data collection would require an additional public comment period, which would delay implementation. Both Committees see value in the swift implementation of this policy and expressed support for the second option which requires programs to submit documentation attesting to the completion of their review and submission of modifications for all eligible kidney candidates by the end of the timeframe.^{14,15} The Committees support this level of oversight as the OPTN would be able to follow up with programs that have not submitted attestation documentation by the end of the proposed timeframe.

On October 17, 2022 the OPTN Minority Affairs Committee voted to support the second option, which requires programs to submit attestation documentation.¹⁶ The OPTN Kidney Transplantation Committee also voted in support on November 7, 2022.

Scope

The Committees propose that registered Black kidney candidates whose waiting time has been affected by race-inclusive eGFR calculations are within the scope of eligibility to receive eGFR waiting time modifications. This scope targets the population of Black kidney candidates who have been negatively impacted by the common and long-standing use of the Black race variable in the estimation of GFR values.¹⁷ This recommended scope includes registered kidney candidates who qualified for waiting time

¹² OPTN Minority Affairs Committee Meeting Summary, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/>

¹³ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, October 11, 2022. Available at <https://optn.transplant.hrsa.gov/>

¹⁴ OPTN Minority Affairs Committee Meeting Summary, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/>

¹⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 24, 2022. Available at <https://optn.transplant.hrsa.gov/>

¹⁶ OPTN Minority Affairs Committee Meeting Summary, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/>

¹⁷ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, May 26, 2022. Available at https://optn.transplant.hrsa.gov/media/pnadmu11/20220526_mac_ki_egfr_summary.pdf

accrual with eGFR, CrCl, or dialysis criteria as described in *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*.

The previously approved proposal, *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, recognized race as a social construct and an unsuitable proxy for genetic difference that should not be used for clinical decision-making. With national support and research demonstrating that inclusion of the race variable can contribute to late referral for transplant and overall worse CKD outcomes, the Committees proposed that any eGFR calculation used for the purposes of the OPTN must not contain a race-based variable.¹⁸ The Committees have developed this follow-on proposal to provide a pathway for impacted candidates' eGFR values, and subsequently waiting time, to be more reflective of their kidney function, regardless of date of registration. The Committees aim to propose a solution that supports increased equity in access to transplantation for this historically disadvantaged population.¹⁹

The following are examples of registered, affected Black kidney candidates within the scope of eligibility for these proposed eGFR waiting time modifications:²⁰

- Candidate A: not accruing waiting time
- Candidate B: accruing waiting time
- Candidate C: accruing waiting time as of registration date
- Candidate D: accruing waiting time with dialysis criteria

These scenarios were part of the originally proposed scope of candidates. Post public-comment Committee discussions regarding scope can be found in the next section.

Candidate A: not accruing waiting time

Candidate A was registered on the waiting list, but does not meet any qualifying criteria to accrue waiting time described in *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*.²¹ If a candidate's GFR was determined by a race-inclusive eGFR calculation and resulted in the candidate not meeting the GFR threshold for waiting time accrual, the candidate's GFR could be re-estimated with a previously obtained race-neutral calculation to determine if the eGFR value would have met the threshold of 20 or less at an earlier date, as seen in **Figure 1**. In this scenario, the transplant program can demonstrate that the candidate's eGFR would have qualified for waiting time as of 12/1/20 if a race-neutral eGFR had been used at the time, and therefore the candidate's waiting time would begin on December 1, 2020, the qualifying date of the race-neutral eGFR.

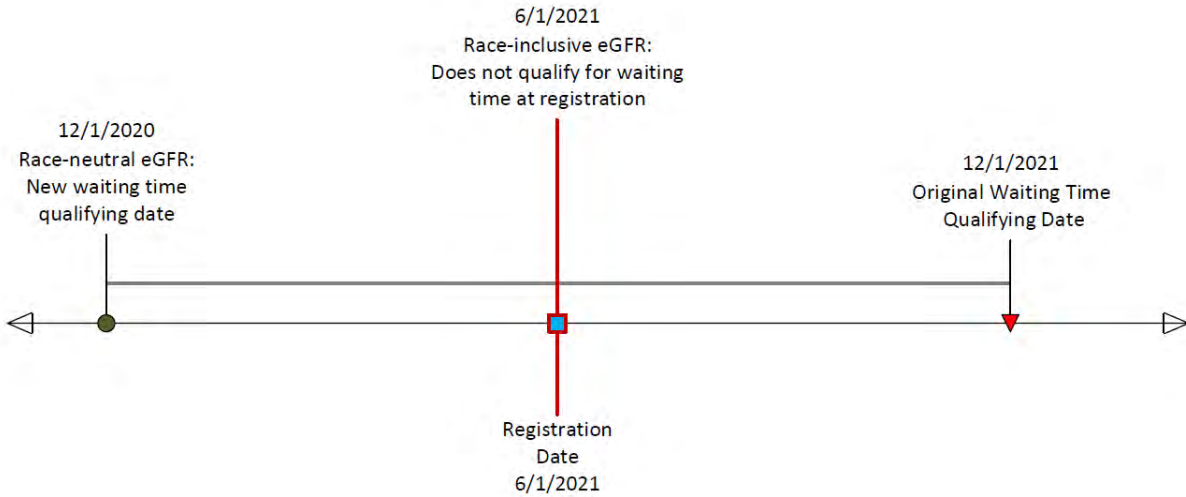
¹⁸ OPTN Public Comment. Establish OPTN Requirement for Race-Neutral eGFR Calculations, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022 https://optn.transplant.hrsa.gov/media/f2qpujia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed June 24, 2022)

¹⁹ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, June 16, 2022. Available at https://optn.transplant.hrsa.gov/media/0izaubsj/20220616_mac_ki_egfr_summary.pdf

²⁰ See Reassess Race in eGFR Calculation Workgroup Meeting Summary May 26, 2022. Available at https://optn.transplant.hrsa.gov/media/pnadmu11/20220526_mac_ki_egfr_summary.pdf

²¹ OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

Figure 1: Candidate A scenario



Candidate B: accruing waiting time

Candidate B was registered on the waiting list and meets the GFR qualifying criteria to accrue waiting time described in *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*.²² If eligibility for waiting time accrual was determined by a race-inclusive eGFR calculation, the candidate’s GFR could be re-estimated with a race-neutral calculation to determine if the eGFR value would have met the threshold of 20 or less at an earlier date, as seen in **Figure 2**. In this scenario, the transplant program can demonstrate that the candidate’s eGFR would have qualified for waiting time as of 12/1/20 if a race-neutral eGFR had been used at the time, and therefore waiting time would begin on December 1, 2020, the qualifying date of the race-neutral eGFR.

²² OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

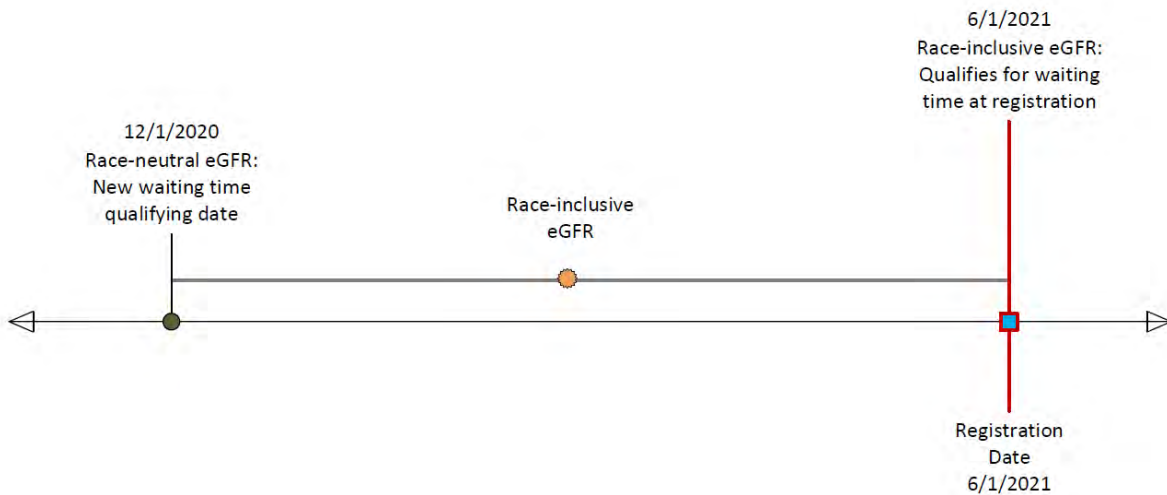
Figure 2: Candidate B scenario



Candidate C: accruing waiting time as of registration date

Candidate C had a qualifying eGFR value prior to registration. Because *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older* requires a candidate’s qualifying eGFR to be the same date or a date after registration, this candidate will begin accruing waiting time on their registration date.²³ If eligibility for waiting time accrual was determined by a race-inclusive eGFR calculation, the candidate’s GFR could be re-estimated with a race-neutral calculation to determine if the eGFR value would have met the threshold of 20 or less at an earlier date, as seen in **Figure 3**. In this scenario, the transplant program can demonstrate that the candidate’s eGFR would have qualified for waiting time as of 12/1/20 if a race-neutral eGFR had been used at the time, and therefore the candidate’s waiting time would begin on December 1, 2020, the qualifying date of the race-neutral eGFR.

Figure 3: Candidate C scenario

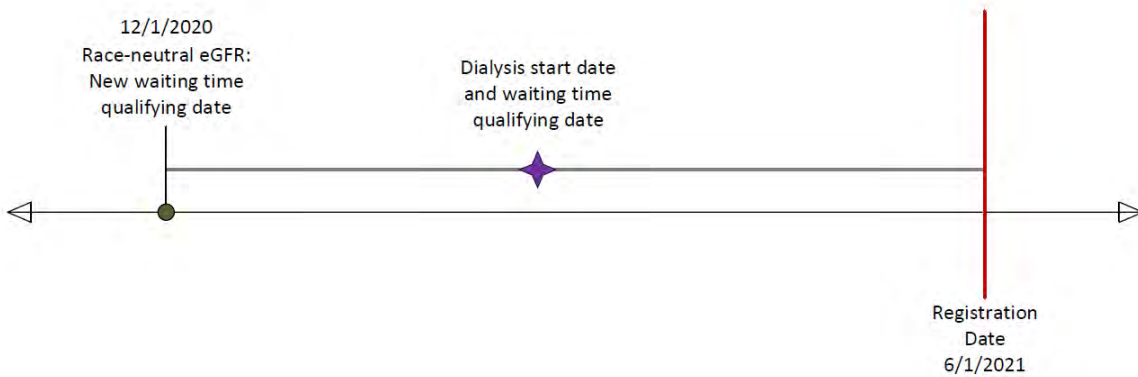


²³OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

Candidate D: accruing waiting time with dialysis date

Candidate D met qualifications for accruing waiting time with dialysis criteria as described in *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*.²⁴ Per this OPTN policy, upon registration, the candidate’s waiting time start date was based on the date that they began dialysis regardless of registration date. If eligibility for waiting time accrual was determined by a race-inclusive eGFR calculation, the candidate’s GFR could be re-estimated with a race-neutral calculation to determine if the eGFR value would have been 20 or less at a date before the dialysis start date, as seen in **Figure 4**. In this scenario, the transplant program can demonstrate that the candidate’s GFR would have qualified for waiting time as of 12/1/20 if a race-neutral eGFR had been used at the time, and therefore the candidate’s waiting time would begin on December 1, 2020, the qualifying date of the race-neutral eGFR.

Figure 4: Candidate D scenario



Post Public Comment Discussions Regarding Scope

As shown in **Figures 1-4**, this proposal recommends that Black kidney candidates qualifying for waiting time using an eGFR value and those qualifying using dialysis criteria are eligible for eGFR waiting time modifications. In addition, those candidates qualifying by Creatinine Clearance (CrCl) criteria may also be eligible.²⁵ The majority of community responses supported this scope as proposed. Feedback in support of the originally proposed scope saw it as an opportunity to positively impact a larger portion of a disadvantaged population. Some feedback expressed support for a more limited scope, which would only allow eGFR or CrCl criteria candidates to qualify for modifications and exclude the dialysis criteria candidates. The Workgroup discussed this decision point and determined they would recommend the wider scope, which is inclusive of those candidates using eGFR, CrCl, and dialysis criteria.²⁶ The Workgroup made this recommendation, as candidates on dialysis can also be affected by the use of race-inclusive eGFR calculations, and members felt they should not be excluded from the qualifying population.

²⁴ OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

²⁵ Ibid.

²⁶ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, October 11, 2022. Available at <https://optn.transplant.hrsa.gov/>

The OPTN Minority Affairs and Kidney Transplantation Committees held similar discussions.^{27,28} Members from both Committees who supported a limited scope, that would allow only candidates who had qualified using eGFR or CrCl criteria, expressed that dialysis candidates should be excluded because some of these candidates may have been disadvantaged by late referral, not the race-inclusive eGFR formula. They explained that late referral can affect all kidney candidates regardless of race, so it should not be considered equitable to only allow candidates with race-inclusive eGFR values to be eligible for eGFR waiting time modifications. Additionally, these members expressed concern for the ability to locate pre-listing lab documentation for dialysis candidates, especially if they were drawn prior to transplant evaluation. Committee members who supported the wider scope, that would include eGFR, CrCl, and dialysis candidates, expressed that a race-inclusive eGFR value could be cause for a late referral, as these candidates could have qualified with the eGFR of 20 or less at an earlier time than their dialysis start date.

The Kidney Committee held additional discussion regarding which Black kidney candidates should be eligible for an eGFR modification.²⁹ While discussing the difference between late access to the waiting list due to late referral and late access to the waiting list due to the use of a race-inclusive eGFR calculation, members explained that candidate eligibility for eGFR waiting time modification should be contingent upon if the documentation of an earlier eGFR value would have taken the candidate from an eGFR value above 20 mL/min with a race-inclusive calculation to an eGFR value below 20 mL/min with a race-neutral calculation. For example, if documentation shows a candidate had an eGFR of 22 mL/min with a race-inclusive eGFR calculation, but has an eGFR of 19 mL/min with a race-neutral eGFR calculation, this candidate will be considered within the scope of eligibility for an eGFR waiting time modification, as seen in **Figure 5**. However, a candidate who had an eGFR of 14 mL/min with a race-inclusive eGFR, but an eGFR of 11 with a race-neutral eGFR, would not be within the scope of eligibility for an eGFR waiting time modification, as seen in **Figure 6**. The Kidney Committee's rationale is that the addition of this qualification to the scope better connects candidates' late access to the wait list to the use of the race-inclusive variable in the eGFR calculation, causing their eGFR value to span above 20 mL/min and then at or below 20 mL/min.

²⁷ OPTN Minority Affairs Committee Meeting Summary, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/>

²⁸ OPTN Kidney Transplantation Committee Meeting Summary, October 24, 2022. Available at <https://optn.transplant.hrsa.gov/>

²⁹ OPTN Kidney Transplantation Committee Meeting Summary, October 14, 2022. Available at <https://optn.transplant.hrsa.gov/>

Figure 5: Candidate eligible for an eGFR waiting time modification



Figure 6: Candidate not eligible for an eGFR waiting time modification



On October 17, 2022 the OPTN Minority Affairs Committee voted to support the wider scope, to include eGFR, CrCl, and dialysis candidates. On November 7, 2022 OPTN Kidney Transplantation Committee voted in support of this recommendation, with the additional scope eligibility requirement as mentioned above. The OPTN Minority Affairs Committee regrouped on November 8, 2022 to discuss this variation on scope and also voted in support.

Documentation

The Committees propose requiring documentation demonstrating candidate eligibility for waiting time accrual at an earlier date due to utilization of a race-inclusive eGFR calculation.³⁰ The Committees recommend that one of the following be provided by transplant programs:

1. Documentation of the candidate’s eGFR values for Black and non-Black candidates
2. Documentation showing both the estimation of GFR with a race-inclusive calculation and a re-estimation of GFR with race-neutral calculation

Option 1: Documentation of the candidate’s eGFR values for Black and non-Black candidates

The Committees propose that in order to demonstrate a candidate’s eligibility for an eGFR waiting time modification, transplant programs should be required to submit a dated lab that reports both eGFR values for Black and non- Black individuals.³¹ National and larger laboratories (e.g. Labcorp, Quest Diagnostics) include values for both Black and non-Black eGFR calculations. The Committees felt this would be an accessible, reliable data source as the documentation itself is objective and it explicitly demonstrates the two differing eGFR values for Black and non-Black candidates. This documentation also is required to include the date and time of GFR estimation. **Figure 7** shows a lab report with Black and non-Black eGFR values, and is an example of this required documentation.

Figure 7: Example documentation of the candidate’s eGFR values for Black and non-Black candidates example

LabCorp Example

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
BUN+Creat					
BUN	10		mg/dL	6 - 24	01
Creatinine, Serum	0.67		mg/dL	0.57 - 1.00	01
eGFR If NonAfrican Am	104		mL/min/1.73	>59	
eGFR If African Am	120		mL/min/1.73	>59	
BUN/Creatinine Ratio	15			9 - 23	

BUN/Creatinine reference range: BUN (Blood Urea Nitrogen) 6-24 mg/dL; Creatinine 0.57-1.00 mg/dL; BUN/Creatinine Ratio 9-23; eGFR (estimated Glomerular Filtration Rate) >59 mL/min/1.73 (results will show variations for African American and Non African American)

Option 2: Documentation showing both the estimation of GFR with a race- inclusive calculation and a re-estimation of GFR with race-neutral calculation

The Committees acknowledged that not all transplant programs use national or large laboratories to conduct eGFR testing. For transplant programs that use in-house or small laboratories, the Committees recommend that two documents be required to demonstrate a candidate’s eligibility for an eGFR waiting time modification.³² The first document is a lab report showing estimation of a candidate’s GFR

³⁰ OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

³¹ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, June 1, 2022. Available at https://optn.transplant.hrsa.gov/media/rkwnmaws/20220601_mac_kidney_egfr-wt-mods_summary.pdf

³²Ibid.

with a race-inclusive calculation, including the date and time of estimation. The second document is evidence of re-estimation of the candidate’s GFR with any race-neutral eGFR calculation demonstrating a qualifying value. A variety of race-neutral eGFR calculators can be found online. **Figure 8** and **Figure 9** show examples of the second piece of required documentation.

Figure 8: Re-estimation of GFR with race-neutral calculation example 1

Serum Creatinine: mg/dL μmol/L

Serum Cystatin C: mg/L

Age: Years

Gender: Male Female

Standardized Assays: Yes No Not Sure

Adjust for body surface area: Yes No Not Sure

Calculate

Figure 9: Re-estimation of GFR with race-neutral calculation example 2

Glomerular Filtration Rate (GFR) Estimate by MDRD 4-Variable Equation

[Share](#)

Sex: Female Male

Age (years):

Black Race: No Yes

Serum Creatinine (mg/dL):

GFR: mL/min/1.73 m²

Alignment with Establish OPTN Requirement for Race- Neutral eGFR Calculations

The Committees discussed requiring the 2021 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) calculation for submission of eGFR waiting time modifications, as it is a modern, nationally recommended method of estimating GFR.³³ Ultimately, the Committees determined it permissible for

³³ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, June 1, 2022. Available at https://optn.transplant.hrsa.gov/media/rkwnmaws/20220601_mac_kidney_egfr-wt-mods_summary.pdf

programs to use any race-neutral eGFR calculation to support an eGFR waiting time modification request.³⁴ They agreed that although this proposal is separate from *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, the two proposals should be aligned. The Committees discussed that prospective candidates who will be listed with any race-neutral eGFR calculation and registered candidates affected by race-inclusive eGFRs should be treated similarly, with regards to not specifying which race-neutral eGFR calculation should be used.

Post Public Comment Discussions Regarding Documentation

There was no post public comment discussions regarding this documentation.³⁵ The Committees reaffirmed the documentation requirements as proposed.

Timeframe

The Committees proposed a temporary, 365 day timeframe to allow transplant programs to assess their waiting lists and submit eGFR waiting time modifications for affected candidates.³⁶ They recommend this time period to give transplant programs enough time to be informed of this opportunity, assess their waiting lists for qualifying candidates, and submit eGFR waiting time modification requests with the required documentation.

The Committees also recommend that programs should be permitted to submit eGFR waiting time modifications for candidates listed during the 365 day period. *Establish OPTN Requirement for Race-Neutral eGFR Calculations* will require these candidates to be listed with a race-neutral eGFR calculation, but the Committees wanted to include these newly registered candidates to ensure that if they had previously been impacted by the use of a race-inclusive eGFR calculation, they would also be eligible for a waiting time modification.³⁷ Should they submit the required documentation before the policy sunset date, affected candidates listed during the 365 day timeframe should be considered for eGFR waiting time modifications.

Post Public Comment Discussions Regarding Timeframe

Public comment sentiment was mixed regarding the proposed 365 day timeframe for submission of eGFR modifications. Some responses indicated support for the proposed timeframe, while others suggested that it should be longer than 365 days, shorter than 365 days, or that there should be no timeframe on this policy. Both Committees felt that this policy should have a timeframe because without a deadline, programs' completion of eGFR waiting time modifications for all affected kidney candidates could not be enforced. Members also felt that any amount of time over 365 days would be too long for candidates to wait to receive eGFR waiting time modifications, but that 6 months would be too short to expect programs to meet the policy requirement, especially with additional recommendations to include candidate notification and attestation reporting. The Committees recommend that 365 days is the correct timeframe for programs to be informed of this opportunity,

³⁴ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, June 16, 2022. Available at https://optn.transplant.hrsa.gov/media/0izaubsj/20220616_mac_ki_egfr_summary.pdf

³⁵ OPTN Public Comment. Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations, OPTN Minority Affairs and Kidney Transplantation Committees, August 2022. https://optn.transplant.hrsa.gov/media/mcgfora4/mod-candidate-wait-time-date-aff-by-race-based-egfr-calcs_kid-mac_pc-summer-2022.pdf (accessed October 28, 2022)

³⁶ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, May 26, 2022. Available at https://optn.transplant.hrsa.gov/media/pnadmu11/20220526_mac_ki_egfr_summary.pdf

³⁷ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, June 1, 2022. Available at https://optn.transplant.hrsa.gov/media/rkwnmaws/20220601_mac_kidney_egfr-wt-mods_summary.pdf

assess their waiting lists for qualifying candidates, submit eGFR waiting time modification requests with the required documentation, send candidate notifications, and submit attestation documentation.^{38,39}

On October 17, 2022 the OPTN Minority Affairs Committee voted to support a 365 day timeframe. The OPTN Kidney Transplantation Committee also voted in support on November 7, 2022.

Waiting time application information

To operationalize eGFR waiting time modifications, the transplant programs will need to provide the following information to the OPTN

- Candidate name
- Candidate SSN
- Transplant program name/code
- Required Documentation
- Transplant physician/surgeon signature
- Transplant physician/surgeon name
- Transplant program contact name
- Transplant program contact email
- Transplant program contact phone number

The Committees propose that this information be provided by transplant programs on an OPTN eGFR Waiting Time Modification Form and submitted to the OPTN. The Committees recommend requiring this information as it is minimum information they found necessary to identify the candidate and determine the amount of waiting time the impacted candidate could receive. This proposed information aligns with the fields currently used on other OPTN waiting time modification forms.⁴⁰ This information will be collected on a temporary basis, during the 365 day timeframe. The Committees have informed and consulted with the Data Advisory Committee (DAC) on this temporary data collection. There was no public comment feedback from the community on the waiting time application information.

Post Public Comment Discussions Regarding waiting time application information

There was no post public comment discussions regarding waiting time application information. The Committees re-affirmed the waiting time application information requirements as proposed.

Candidate notification

During public comment, there was strong support for the addition of a requirement to notify kidney transplant candidates of this policy change and the status of their eligibility for an eGFR waiting time modification.⁴¹ The Workgroup agreed with this feedback and recommended that all candidates be

³⁸ OPTN Minority Affairs Committee Meeting Summary, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/>

³⁹ OPTN Kidney Transplantation Committee Meeting Summary, October 24, 2022. Available at <https://optn.transplant.hrsa.gov/>

⁴⁰ OPTN Waiting Time Modification Form

⁴¹ OPTN Public Comment. Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations, OPTN Minority Affairs and Kidney Transplantation Committees, August 2022. https://optn.transplant.hrsa.gov/media/mcgfora4/mod-candidate-wait-time-date-aff-by-race-based-egfr-calcs_kid-mac_pc-summer-2022.pdf (accessed October 28, 2022)

notified that their waiting time will be assessed for eGFR waiting time modification eligibility. The addition of a requirement for candidate notification was discussed further by each of the Committees.

On October 17, 2022, the Minority Affairs Committee discussed the inclusion of notification to candidates as a requirement of the policy.⁴² Members discussed the idea of requiring programs to notify candidates both before and after assessment of their waiting lists, but also considered the administrative burden this may cause. The Minority Affairs Committee voted in support of requiring programs to notify all candidates once, at the conclusion of assessing their respective lists. This notification would inform candidates of the policy change, their eGFR waiting time modification eligibility status, and provide an opportunity for candidates to bring forth any additional documentation for consideration. The Committee recommended one candidate notification to decrease administrative burden, but also supports candidates coming forth with other supporting documentation at any time.

On November 7, 2022 the Kidney Committee voted in support of a requirement for transplant programs send two notifications to candidates.⁴³ The first notification would be sent to all kidney candidates for the purpose of transparency and awareness. This notification would invite candidates to bring forth any supporting documentation for consideration. The second notification would be sent to only those candidates registered as Black or African American in the OPTN Computer System and inform these candidates of their eGFR waiting time modification eligibility status. Members agreed that the importance of transparency and benefit of candidate awareness outweighed the administrative burden an additional candidate notification may cause. The OPTN Minority Affairs Committee regrouped on November 8, 2022 to consider the Kidney Committee's recommendation for two candidate notifications. The Minority Affairs Committee discussed the importance of complete transparency with the transplant community and voted in support of two candidate notifications, similar to the Kidney Committee. However, their vote included the recommendation for the second candidate notification to be sent to all kidney transplant candidates, not exclusively those who are registered in the OPTN Computer System as Black or African American. On November 10, 2022 Kidney Committee members were sent a communication to inform them of the Minority Affairs Committee's thoughts on requiring that a second notification be sent to all registered kidney candidates. The OPTN Kidney Transplantation Committee members voted in support in November 12, 2022.

Overall Sentiment from Public Comment

The Committees welcomed all input on *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations*, but asked for the following specific feedback during public comment:

- Do community members agree with the proposed eGFR waiting time modification pathway?
- Do community members propose an alternative eGFR waiting time modification pathway?
- What kind of education resources would assist programs in participating?
- What potential unintended consequences or challenges should be considered during this proposal's development? Do those consequences or challenges outweigh the benefits of the proposed waiting time modification pathway?
- Are there other waiting time modification scenarios that the members would like the committees to consider?
- Does the community agree with the proposed scope, timeframe and required documentation?

⁴² OPTN Minority Affairs Committee Meeting Summary, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/>

⁴³ OPTN Kidney Transplantation Committee Meeting Summary, October 24, 2022. Available at <https://optn.transplant.hrsa.gov/>

The proposal received 199 sentiment responses. Of these responses, 41 were substantive, including 6 comments from OPTN Committees and 5 comments from organizations and societies. These comments represent all member types, with the greatest participation coming from transplant programs, which is similar to other OPTN proposals. The proposal was generally supported in public comment. The opposition expressed is likely related to public comment feedback that supports requiring all transplant programs to submit eGFR waiting time modifications for affected candidates.

Figure 10 shows sentiment received from all respondents (regional meeting, online, and email) by their stated member type. Most member types supported or strongly supported the proposal, demonstrated by a sentiment score of 4.4 (support illustrated by green shaded bars). The minority of respondents expressed opposition. The opposing few included representation from general public, Organ Procurement Organizations (OPOs), patients, and transplant hospital member types. One member who expressed strong opposition represented a transplant hospital.

**Figure 10: Sentiment by member type,
Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations**

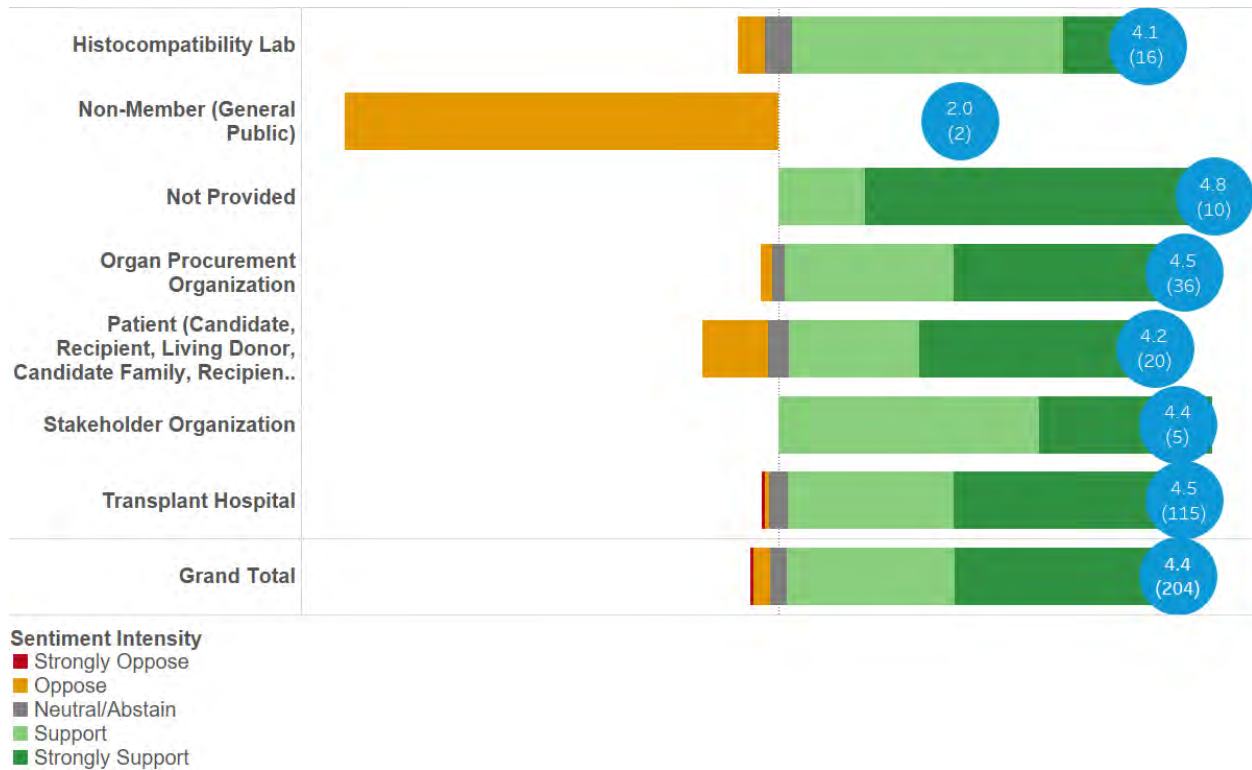
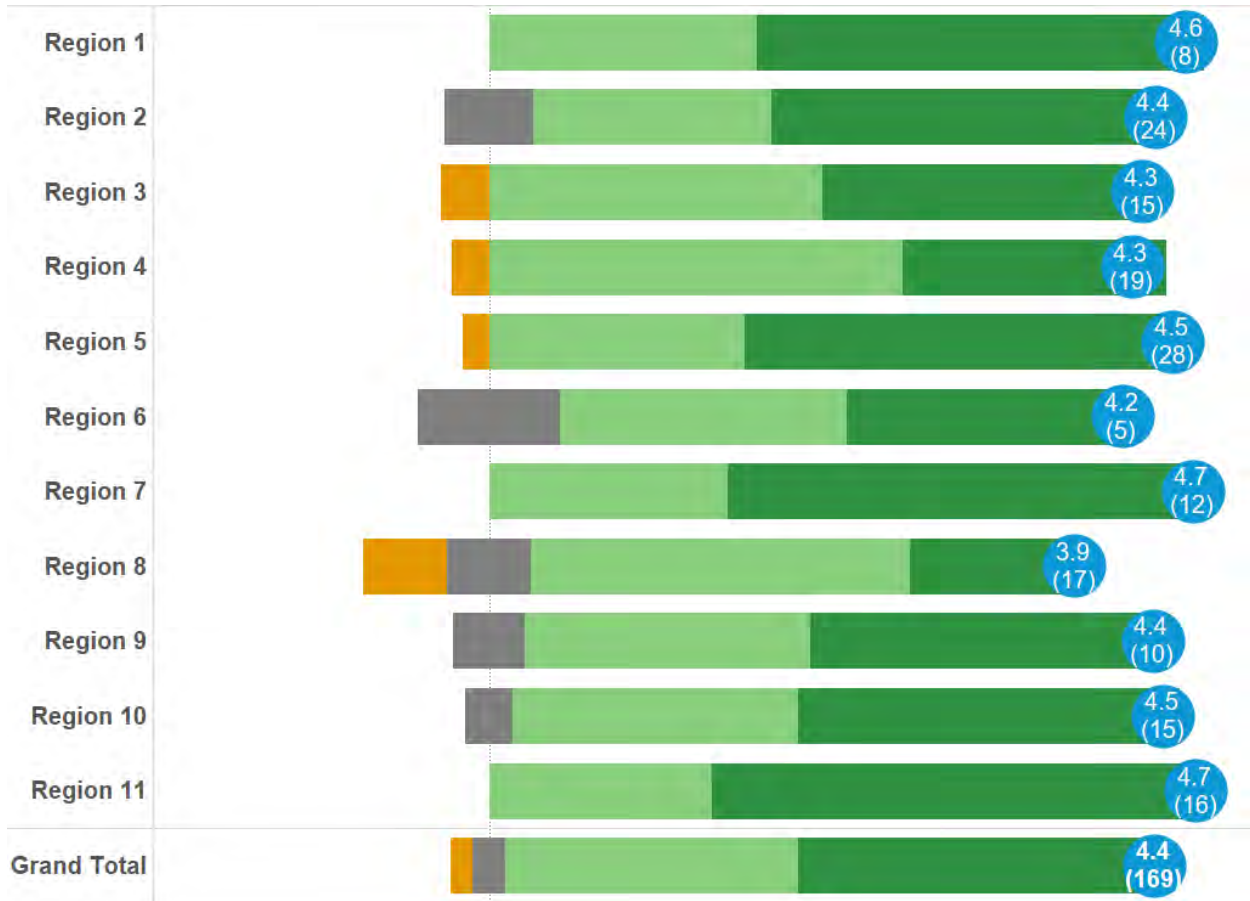


Figure 11 shows sentiment received during regional meetings. Again, overall sentiment was supportive or strongly supportive, as indicated by a total sentiment score of 4.4. A few respondents in regions 3, 4, and 5 expressed opposition.

**Figure 11: Sentiment by region,
Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations**



Sentiment Intensity
■ Strongly Oppose
■ Oppose
■ Neutral/Abstain
■ Support
■ Strongly Support

Themes

In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit a substantive written comment. Responses are submitted by members of the public at large, as well as on behalf of regions and committees. Commenters covered many different topics, including the following themes.

Mandate modifications

The proposal presented the modification of waiting time for Black kidney candidates affected by race-based eGFR calculations not as a requirement, but as a voluntary opportunity for transplant programs. The most frequent feedback received on this proposal is that all transplant programs should be required

to assess their waiting lists and submit of eGFR waiting time modifications on behalf of affected candidates.

Scope

The majority of respondents supported the proposed scope which includes 1) candidates who qualify to begin accruing waiting time with eGFR or CrCl and 2) candidates qualify using dialysis criteria. Some feedback indicated support for limiting the scope to only the eGFR or CrCl criteria candidates.

Timeframe

The proposal received mixed feedback regarding the recommended 365 day timeframe for submission of eGFR modifications. Some responses indicated support for the proposed timeframe, while others suggested that it should be longer than 365 days, shorter than 365 days, or that there should be no timeframe.

Candidate notification

Feedback on the proposal indicated support for increased transparency through clear communication with candidates regarding this policy. Input also suggested notifying those candidates who qualified for an eGFR modification.

Educational resources

Input that responded to the Committees' request for feedback about educational resources suggested that both transplant programs and candidates will seek guidance on the eGFR waiting time modification process.

Administrative demand

The proposal received some feedback suggesting that its implementation could contribute to an increase of administrative burden and challenges.

Compliance Analysis

NOTA and OPTN Final Rule

The OPTN Minority Affairs and Kidney Transplantation Committees submit the following project for consideration under the authority of NOTA, which requires the OPTN to "establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,"⁴⁴ and the OPTN Final Rule, which states the OPTN shall develop "Policies for the equitable allocation of cadaveric organs in accordance with §121.8."⁴⁵ This proposal impacts allocation of organs because using a Black race variable overestimates eGFR values, which can delay the accrual of waiting time, which could impact a candidate's placement on the match run. Approved eGFR waiting time

⁴⁴ 42 USC §274(b)(2)(B)

⁴⁵ 42 CFR §121.4(a)(1)

modifications impact the allocation of organs because the candidates who receive waiting time back may achieve additional priority related to their waiting time accrual, impacting candidate placement on the match run.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”⁴⁶ This proposal:

- **Is based on sound medical judgment.**⁴⁷ The data and literature show that inclusion of the Black race coefficient in eGFR calculations overestimates Black kidney candidates’ eGFR values.⁴⁸ It also supports that if race-neutral eGFR calculations are required, the severity of Black kidney candidates’ illness will be recognized and promote more timely referral for kidney transplantation and the initiation of qualifying waiting time.⁴⁹ The proposed solution is the most ideal method for operationalizing eGFR waiting time modifications, as it allows the OPTN to provide approved candidates with the exact amount of waiting time they would have received if a race-neutral eGFR calculation had been used. The amount of time an approved candidate could receive varies greatly and is dependent upon individual factors. Providing a standard amount of time to each approved candidate was considered, but determined not an appropriate solution due to its inability to discriminate how much time each candidate should receive. The proposed solution is the most accurate way to promote equity in access to kidney transplantation to impacted Black kidney candidates.
- **Is designed to...promote patient access to transplantation**⁵⁰ by giving similarly situated candidates equitable opportunities to receive an organ offer. Allowing transplant programs to modify waiting time for Black candidates based on the use of an eGFR calculation will allow kidney candidates with similar degrees of medical urgency to have equal opportunities to receive an organ offer based on waiting time accrual, independent of candidates’ race.
- This proposal is not based on the candidate’s place of residence or place of listing.⁵¹

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Is designed to avoid futile transplants⁵²
- Is designed to avoid wasting organs⁵³

⁴⁶ 42 CFR §121.8(a)

⁴⁷ 42 CFR §121.8(a)(1)

⁴⁸ OPTN Public Comment. *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022 https://optn.transplant.hrsa.gov/media/f2qpujia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed June 24, 2022)

⁴⁹ Ibid.

⁵⁰ 42 CFR §121.8(a)(5)

⁵¹ 42 CFR §121.8(a)(8)

⁵² 42 CFR §121.8(a)(5)

⁵³ Ibid.

- Is designed to achieve the best use of donated organs⁵⁴
- Promotes the efficient management of organ placement⁵⁵

The Committee also submits this data collection proposal under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the Organ Procurement and Transplantation Network (OPTN) to “collect, analyze, and publish data concerning organ donation and transplants,”⁵⁶ and the Final Rule requires the OPTN to “maintain records of all transplant candidates, all organ donors and all transplant recipients.”⁵⁷ For 365 days, transplant programs would provide additional information on particular transplant candidates that are eligible for waiting time modifications under this proposal.

OPTN Strategic Plan

Improve equity in access to transplants:

This proposal intends to improve equity in access to transplants by addressing equity for Black kidney transplant candidates. This proposed policy change requires kidney transplant programs to review their waiting lists to determine if modifications are necessary for candidates who could have begun accruing waiting time at an earlier date according to *OPTN Policy: 8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older* if a race-neutral eGFR calculation was used. This change intends to improve accuracy in estimation of GFR for Black kidney transplant candidates and make their eGFR values more reflective of actual kidney function.

Implementation Considerations

Transplant Programs

Operational Considerations

This proposal would require transplant programs to submit eGFR waiting time modifications for their impacted candidates. Transplant programs would be responsible for:

- Assessment of their own kidney transplant waiting lists and candidate clinical information, gathering required data and documentation for each affected candidate, and submitting requests for waiting time modifications
- Submitting documentation attesting to the completion of kidney transplant waiting list assessment and submission of modifications for potentially affected candidates
- Notifying candidates, details to be determined

Fiscal Impact

Fiscal impact on transplant hospitals could include increased administrative resources related to assessment of waiting list and submission of eGFR waiting time modification for eligible candidates, and candidate notification and attestation documentation requirements.

⁵⁴ 42 CFR § 121.8(a)(2)

⁵⁵ 42 CFR § 121.8(a)(5)

⁵⁶ 42 USC §274(2)(l)

⁵⁷ 42 CFR § 121.11 (a) (1)

Organ Procurement Organizations

Operational Considerations

This proposal is not anticipated to affect the operations of Organ Procurement Organizations.

Fiscal Impact

There is no expected fiscal impact for organ procurement organizations.

Histocompatibility Laboratories

Operational Considerations

This proposal is not anticipated to affect the operations of Histocompatibility Laboratories.

Fiscal Impact

There is no expected fiscal impact for histocompatibility laboratories.

OPTN

Operational Considerations

The OPTN will plan for communication with its members to make them aware of this opportunity and provide educational materials regarding the modification submission process. The OPTN will review complete modification submission requests, and process the approved waiting time modifications.

Resource Estimates

The OPTN contractor estimates 490 hours for implementation. Implementation will involve updates to the OPTN Computer system to provide a new eGFR waiting time modification form, education and training on the changes, and communication efforts about the changes. The OPTN contractor estimates 375 hours for ongoing support. Ongoing support includes reviewing and processing completed modification submission requests, and monitoring and collecting required attestations.

Post-implementation Monitoring

Member Compliance

Members will be expected to comply with requirements in the proposed policy language. In addition to the compliance monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested. The proposed language will not change the current routine monitoring of OPTN members.

The OPTN will review the submission of all required documentation and will refer any transplant programs found not in compliance with the policy requirements at the end of the 365-day period to the Membership and Professional Standards Committee (MPSC). The MPSC will review all relevant information to determine if a policy violation has occurred and what type of action is warranted.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”⁵⁸ This policy will be evaluated at approximately six months and one year post-implementation.

Metrics to be evaluated include:

- Number of modifications by complete vs. incomplete status
- The distribution of the amount of waiting time awarded to modified registrations
- Number of modified registrations by registration year and month
- Summary of demographics of candidates with modified registrations

Conclusion

The use of race-inclusive eGFR calculations has shown to have an overall negative impact on Black kidney transplant candidates, including delayed initiation of waiting time accrual.⁵⁹ The Committees propose that transplant programs be required to assess their kidney waiting lists, submit eGFR modification requests for potentially impacted registered Black kidney candidates with supporting documentation, send candidate notifications, and submit attestation documentation to the OPTN within a 365 day timeframe. The Committees present this proposal to provide restorative justice and increase equity in access to transplantation for Black kidney candidates who have been disadvantaged by the use of race-based eGFR calculations.

⁵⁸ 42 CFR §121.8(a)(6)

⁵⁹ OPTN Public Comment. *Establish OPTN Requirement for Race- Neutral eGFR Calculations*, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022 https://optn.transplant.hrsa.gov/media/f2qpjia/establish-optn-requirement-for-race-neutral-egfr-calculations_winter-2022-pc.pdf (accessed June 24, 2022)

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **3.7.D Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR** 2 **Calculations**

3 **3.7.D.i Notification Requirement**

4 All designated kidney transplant programs must notify every candidate registered at the transplant
5 program of the responsibilities of the program pursuant to *Policy 3.7.D: Waiting Time Modifications for*
6 *Kidney Candidates Affected by Race-Inclusive eGFR Calculations.*

7 **3.7.D.ii Determination of Eligible Candidates**

8 All designated kidney transplant programs must determine eligibility for a Waiting Time Modification for
9 Kidney Candidates affected by Race-Inclusive eGFR Calculations for each candidate registered at the
10 transplant program. A candidate is eligible for a waiting time modification if the candidate is registered
11 as Black or African-American in the OPTN Computer system and has documentation establishing that the
12 candidate had an eGFR that was over 20 mL/min and would have been 20 mL/min or less if a race-
13 neutral calculation had been used.

14 **3.7.D.iii Application for Waiting Time Modification**

15 Transplant programs must submit an eGFR waiting time modification for each eligible candidate
16 registered at their transplant program. The application for an eGFR waiting time modification must
17 include the qualifying eGFR value, as well as:

- 18 1. Documentation of one of the following:
19 • The candidate's eGFR values for Black and non-Black candidates or
20 • The estimation of GFR with a race-inclusive calculation and a re-estimation of GFR with a race-
21 neutral calculation
22 2. The name and signature of the candidate's physician or surgeon.
23

24 Upon receipt of a complete application the OPTN will implement the waiting time modification.

25 **3.7.D.iv Reporting Requirements for Kidney Transplant Programs**

26 All designated kidney transplant programs must submit an attestation to the OPTN by January 3, 2024,
27 signed by the transplant program director (or their designee), affirming that the program has completed
28 both of the following:

- 29 • Notification to all candidates registered at the transplant program of their eligibility for a
30 waiting time modification according to this policy and

31
32

- Submission of eGFR waiting time modifications for all eligible candidates registered at the transplant program.

#