

Public Comment Proposal

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

OPTN Minority Affairs and Kidney Transplantation Committees

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

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

Affected Policy: 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

Sponsoring Committee: Minority Affairs and Kidney Transplantation

Public Comment Period: August 3, 2022- September 28, 2022

Executive Summary

In winter 2022, the OPTN Minority Affairs and Kidney Transplantation Committees (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, to be implemented on July 27, 2022.

The Committees submit this follow-on proposal to provide programs a 365 day timeframe to request eGFR waiting time modifications for Black kidney candidates impacted by race-inclusive eGFR calculations. This paper outlines the Committees' recommended candidate scope, required documentation, and timeline.

¹ 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 9, 2022)

Purpose

This proposal's purpose is to address waiting time modification for Black kidney candidates that are registered on the kidney transplant waiting list who have been affected by race-inclusive eGFR calculations. When the policy to *Establish OPTN Requirement for Race-Neutral eGFR Calculations* 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 policy states that GFR qualifying waiting time begins on or after the candidate's registration date.² This paper proposes a pathway that would allow transplant hospitals to request an earlier eGFR qualifying date, regardless of a candidate's registration date. Changes proposed by this paper would provide programs the opportunity to request eGFR waiting time modifications for registered candidates, as not to disadvantage these individuals based upon date of registration.

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.

These GFR and dialysis criteria are used for initiation of waiting time accrual and 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,

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.

the sooner they will receive access to a transplant absent other qualifying criteria.⁸ The OPTN also uses GFR thresholds as qualifying criteria in several other policies.⁹

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.¹⁰ Community responses indicated interest in the concept, but did not provide further input on how eGFR waiting time modifications should be operationalized.¹¹ 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 develop this proposed equity-driven solution.¹²

Overview of Proposal

The OPTN Minority Affairs and Kidney Transplantation Committees propose updating policy to allow transplant programs with Black kidney candidates who were affected by race-inclusive eGFR calculations to request 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' proposed recommendations for the scope, timeline, and supporting documentation requirements for eGFR waiting time modification requests.

Scope

The Committees propose that registered Black kidney candidates whose waiting time has been affected by race-inclusive eGFR calculations are considered within the scope of eligibility to receive eGFR waiting time modifications. Members recommended this relatively narrow scope in order to target the population of Black candidates who could have been negatively impacted by the common and long-standing use of the Black race variable in estimation of GFR values.¹³ 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 Chronic Kidney Disease (CKD) outcomes, the Committees proposed that any eGFR calculation used for the purposes of the OPTN must not contain a race-based

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

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 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)

¹¹ 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)

¹² See Reassess Race in eGFR Calculation Workgroup Meeting Summary, May 3, 2022. Available at https://optn.transplant.hrsa.gov/media/ldkpic3l/20200503_mac_ki_egfrwtmods_summary.pdf

¹³ 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

variable.¹⁴ 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.¹⁵

The following are examples of registered impacted Black kidney candidates within the scope of eligibility for these proposed eGFR waiting time modifications:¹⁶

- 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

¹⁴ 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)

¹⁵ 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

¹⁶ 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

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*.¹⁷ If a candidate's GFR was determined by a race-inclusive eGFR calculation and resulted in the candidate not meeting the GFR threshold to for waiting time accrual, 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 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.

Figure 1: Candidate A scenario



¹⁷ *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*

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*.¹⁸ 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.

Figure 2: Candidate B scenario



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

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 at a date after registration, this candidate will begin accruing waiting time on their registration date.¹⁹ 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



¹⁹OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older

Candidate D: Accruing waiting time with dialysis criteria

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*.²⁰ 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.²¹ 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



Documentation

The Committees propose requiring documentation demonstrating candidate eligibility for waiting time accrual at earlier date due to race-inclusive eGFR calculation.²² 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

²⁰ *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*

²¹ *Ibid.*

²² 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

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.²³ 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.²⁴ This documentation also is required to include the date and time of GFR estimation. **Figure 5** shows a lab report with Black and non- Black eGFR values, and is an example of this required documentation.

Figure 5: 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 Africn 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.²⁵ The first document is a lab report showing estimation of a candidate’s GFR 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.²⁶ A variety of race-neutral eGFR calculators can be found online. **Figure 6** and **Figure 7** show examples of the second piece of required documentation.

²³ 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

²⁴ Ibid.

²⁵ Ibid.

²⁶ Ibid.

Figure 6: 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 7: Re-estimation of GFR with race-neutral calculation example 2

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

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 CKD-EPI calculation for submission of eGFR waiting time modifications, as it is a modern, nationally recommended method of estimating GFR.²⁷ Ultimately, the Committees determined it permissible for programs to use any race-neutral eGFR calculation to support an eGFR waiting time modification request.²⁸ They agreed that although this proposal is separate from

²⁷ 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

²⁸ 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

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.²⁹

Timeframe

The Committees propose a temporary, 365 day timeframe to allow transplant programs to submit eGFR waiting time modifications.³⁰ 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.³¹

The Committees also recommend that candidates listed during the 365 day period should also be permitted to submit eGFR waiting time modifications.³² *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.³³ ³⁴ Should they submit the required documentation before policy sunset on the end of the 365th day, affected candidates listed during the 1 year timeframe should be considered for eGFR waiting time modifications.³⁵

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

²⁹ 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

³⁰ 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

³¹ Ibid.

³² 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

³³ Ibid

³⁴ 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)

³⁵ 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

The Committees propose that this information will be provided by transplant programs on an OPTN eGFR Waiting Time Modification Form and submitted to the OPTN.³⁶ 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.³⁷ 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.

NOTA and Final Rule Analysis

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,”³⁸ and the OPTN Final Rule, which states the OPTN shall develop “Policies for the equitable allocation of cadaveric organs in accordance with §121.8.”³⁹ 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 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.”⁴⁰ This proposal is:

- **Is based on sound medical judgment.**⁴¹ The data and literature show that inclusion of the Black race coefficient in eGFR calculations overestimates Black kidney candidates’ eGFR values.⁴² 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.⁴³ 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

³⁶ Ibid.

³⁷ OPTN Waiting Time Modification Form

³⁸ 42 USC §274(b)(2)(B)

³⁹ 42 CFR §121.4(a)(1)

⁴⁰ 42 CFR §121.8(a)

⁴¹ 42 CFR §121.8(a)(1)

⁴² 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)

⁴³ Ibid.

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 transplantation⁴⁴** 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.⁴⁵

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 transplants⁴⁶
- Is designed to avoid wasting organs⁴⁷
- Is designed to achieve the best use of donated organs⁴⁸
- Promotes the efficient management of organ placement⁴⁹

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,"⁵⁰ and the Final Rule requires the OPTN to "maintain records of all transplant candidates, all organ donors and all transplant recipients."⁵¹ For 365 days, transplant programs would provide additional information on particular transplant candidates that are eligible for waiting time modifications under this proposal.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

This proposal would provide transplant programs with the opportunity 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.

⁴⁴ 42 CFR §121.8(a)(5)

⁴⁵ 42 CFR §121.8(a)(8)

⁴⁶ 42 CFR §121.8(a)(5)

⁴⁷ *Ibid.*

⁴⁸ 42 CFR § 121.8(a)(2)

⁴⁹ 42 CFR § 121.8(a)(5)

⁵⁰ 42 USC §274(2)(I)

⁵¹ 42 CFR § 121.11 (a) (1)

Operations affecting the OPTN

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.

Operations affecting Histocompatibility Laboratories

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

Operations affecting Organ Procurement Organizations

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

Potential Impact on Select Patient Populations

The Final Rule requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies.”⁵² If approved, this policy could improve access to transplantation for Black kidney candidates by more appropriately prioritizing them amongst all other candidates awaiting kidney transplantation by permitting them to adjust their waiting time.

The Committees discussed the need for transition procedures upon the policy’s implementation. They considered that in any instance when an allocation change is made, some populations will experience increased access and others decreased access. The Committees identified that non-Black candidates will be “treated less favorably” because their waiting time might not hold as much priority once Black candidates’ times are adjusted. They did not recommend special transition procedures, as this proposal is intended to correct an existing disadvantage for Black candidates.⁵³ This follow on proposal aims to focus on the population of candidates that were not addressed by the *Establish OPTN Requirement for Race-Neutral eGFR* project in order to include all candidates affected by race-inclusive eGFR calculations.

Projected Fiscal Impact

The proposal is expected to have only a minimal fiscal impact on organ procurement organizations (OPOs), transplant hospitals, or histocompatibility laboratories.

Projected Impact on Transplant Hospitals

There is expected to be minimal fiscal impact on transplant hospitals as a result of the small number of patients at each hospital who are expected to be eligible for additional waiting time. Review of patient records would be minimal and could likely be part of standard hospital operations. The potential improved access to transplantation also outweighs the minimal costs.

Projected Impact on the OPTN

The OPTN will monitor and process submitted eGFR waiting time modifications.

⁵² 42 CFR § 121.8 (d)(1)

⁵³ 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

Projected Impact on Organ Procurement Organizations

There is no expected fiscal impact for organ procurement organizations.

Projected Impact on Histocompatibility Labs

There is no expected fiscal impact for histocompatibility laboratories.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”⁵⁴

This proposal will not change current routine monitoring of OPTN members. The OPTN will continue to monitor GFR values entered into the OPTN Computer System based on the criteria outlined in OPTN Policy.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”⁵⁵

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.⁵⁶ The Committees submit this proposal to address scenarios in which a race-inclusive eGFR calculation may have been used to register Black kidney candidates. This proposal would allow transplant programs to assess their kidney waiting lists and submit requests for modification of waiting time based on the difference in candidate eGFR values when a race variable is not included in the eGFR Calculation. This proposal aims to more accurately estimate affected candidates' GFRs and provide a pathway to regain any time lost due to race-inclusive eGFR calculations.

⁵⁴ 42 CFR §121.8(a)(7)

⁵⁵ 42 CFR §121.8(a)(6)

⁵⁶ 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)

Considerations for the Community

- 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?

Policy Language

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

3 Transplant programs may submit a waiting time modification for candidates who were unable to begin
4 accruing waiting time according to *Policy 8.4.A Waiting Time for Candidates Registered at Age 18 Years*
5 *or Older* at an earlier date due to the use of an eGFR calculation that included a race variable.

6 To apply for a waiting time modification, the candidate's transplant program must submit the qualifying
7 eGFR value in an application to the OPTN that includes:

8 1. One of the following:

- 9 • Documentation of the candidate's eGFR values for Black and non-Black candidates or
10 • Documentation showing both the estimation of GFR with a race- inclusive calculation and a re-
11 estimation of GFR with race-neutral calculation

12 2. The name and signature of the candidate's physician or surgeon.

13

14 Upon receipt of a complete application and the required supporting documentation the OPTN will
15 implement the waiting time modification for the candidate.

16

17 *This policy expires 365 days following its implementation.*

18

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