

Public Comment Proposal

Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations

OPTN Minority Affairs and Kidney Transplantation Committees

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Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations

Affected Policies:

1.2: Definitions

3.6. B. i: Non- function of a kidney transplant

8.4. A: Waiting Time for Candidates Registered at Age 18 Years or Older

8.5. G: Prioritization for Liver Recipients on the Kidney Waiting List

9.5. H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

9.9. B: Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older

13.6. A: Requirements for Match Run Eligibility for Candidates

13.7. G OPTN KPD Waiting Time Reinstatement

Sponsoring Committees:

Minority Affairs and Kidney Transplantation

Public Comment Period:

January 27, 2022 – March 27, 2022

Executive Summary

In summer 2021, the sponsoring committees released the *Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation Request for Feedback (RFF)* which solicited community input on potential changes to OPTN policy to restrict the use of the Black race coefficient in eGFR calculations.¹ Requested feedback included information about programs' current use of eGFR and potential impacts of a shift to race-neutral eGFR calculations. The RFF asked the community to bring forth any possible implementation challenges and unintended consequences that should be considered during the proposal's development. The paper also sought the valuable input of patients.²

The feedback received during the OPTN summer 2021 public comment period was used to develop this proposal to prohibit the use of eGFR calculations that include a race- based variable in OPTN policy. This proposal defines GFR within *OPTN Policy 1.2: Definitions* so that any eGFR calculation that does not include a race- based variable may be used. This requirement for race- neutral calculations intends to more accurately estimate Black kidney candidates' GFR values.

¹ OPTN, Reassess the Inclusion of Race in eGFR Equation, https://optn.transplant.hrsa.gov/media/4782/2021august_-reassess-race-in-egfr_request-for-feedback.pdf (accessed October 26, 2021)

² OPTN, Reassess the Inclusion of Race in eGFR Equation, https://optn.transplant.hrsa.gov/media/4782/2021august_-reassess-race-in-egfr_request-for-feedback.pdf (accessed October 26, 2021)

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. The eGFR value 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 indicate 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 candidate waiting time accrual:⁶

1. The candidate's registration date with a measured or calculated creatinine clearance or GFR less than or equal to 20 mL/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR 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 eGFR and dialysis criteria are used for initiation of wait time accrual and are not required for kidney candidate registration. A transplant program may register a kidney transplant candidate with any GFR value, 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 Unlike adult kidney candidates, pediatric kidney candidates' initiation of wait time accrual is based on the date that the candidate registered on the waiting list regardless of clinical criteria. Pediatric candidates may also qualify with the date they began regularly administered dialysis as an ESRD patient.⁹

Current OPTN policy is not prescriptive as to what methods of GFR measurement or estimation programs should or should not be used when registering kidney candidates.¹⁰ There are several widely used eGFR formulas with varying composition that sometimes include a Black race coefficient. Because current OPTN policy is not prescriptive, equations that include and exclude the race coefficient are currently permitted for OPTN use.

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

⁴Ibid.

⁵Ibid.

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

⁷Organ Procurement and Transplantation Network (2014). The New Kidney Allocation System (KAS) Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf

⁸OPTN Policy 8.3: *Kidney Allocation Score*

⁹ OPTN Policy 8.4.B: *Waiting Time for Candidates Registered prior to Age 18*

¹⁰OPTN Policy 8.4.A: *Waiting Time for Candidates Registered at Age 18 or Older*

The OPTN uses eGFR thresholds as qualifying criteria in several policies. One of two qualifying criteria in *OPTN Policy 3.6. B. i: Non-function of a Transplanted Kidney* uses an eGFR threshold to determine if a candidate's waiting time will be reinstated after kidney graft failure.¹¹ Similarly, two of three qualifying criteria in *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 Years or Older* use such thresholds to determine when a candidate will begin to accrue waiting time.¹² One of two qualifying criteria in *OPTN Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List* uses an eGFR threshold to determine if a candidate will be classified as a prior liver recipient and receive additional kidney priority.¹³ One of three qualifying criteria in *OPTN Policy: 9.5.H: Requirements for Primary Hyperoxaluria Model for End-Stage Liver Disease (MELD) or Pediatric End- Stage Liver Disease (PELD) Score Exceptions* uses an eGFR threshold to determine if a candidate qualifies to receive a MELD or PELD score exception for primary Hyperoxaluria.¹⁴ Current OPTN policy requires the eGFR values in 9.5.H to be estimated by the Modification of Diet in Renal Disease (MDRD) 6 formula. The MDRD6 formula includes a race- based variable.

Introduction and rationale for including Black race in eGFR

Modification of Diet in Renal Disease (MDRD) Study

In 1999, the Modification of Diet in Renal Disease (MDRD) study developed an equation to improve prediction of GFR from serum creatinine concentration. Included in the results of this study were findings that suggested Black race was associated with higher serum creatinine levels at the same measured GFR than for White race.¹⁵ Twelve percent of the study's participants were Black (n = 197) and 88% (n= 1,304) participants were White.¹⁶ This study resulted in assignment of a multiplication factor for Black patients' eGFR values.

Chronic Kidney Disease Epidemiology Collaboration (CKD- EPI)

In 2009, researchers developed the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation as a more accurate method for measuring eGFR.¹⁷ This equation aimed to calibrate and standardize traditional serum creatinine–based measures of kidney function and is currently one of the most widely used formulas.¹⁸ It was developed through analysis of a number of independent studies and combined data from thousands of individuals. Results observed similar racial differences in serum creatinine levels as in the MDRD study. The Black race coefficient in the CKD- EPI equation increases eGFR values by 16% for Black individuals.¹⁹

¹¹ *OPTN Policy 3.6. B. i: Non-function of a Transplanted Kidney*

¹² *OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 or Older*

¹³ *OPTN Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*

¹⁴ *OPTN Policy: 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions*

¹⁵ Levey AS, Bosch JP, Lewis JB, Green T, Rogers N, Roth D. A More Accurate Method To Estimate Glomerular Filtration Rate from Serum Creatinine: A New Prediction Equation. *Annals of Internal Medicine*. 1999. 130(6): 461-470

¹⁶ Ibid.

¹⁷ Levey AS, Stevens LA, Schmid CH, Zhang YP, Castro III AF, Feldman HI, Kusek JW, Eggers P, Van Lente F, Greene T, Coresh J. A New Equation to Estimate Glomerular Filtration Rate. *Annals of Internal Medicine*. 2009. 150(9): 604-612

¹⁸ Ibid.

¹⁹ Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. *American Medical Association*. 2019. 322(2):113-114

Limitations of the original and subsequent study

Recent research suggests that the design of the studies that resulted in development of the Black race coefficient have considerable limitations. Both the MDRD and CKD-EPI studies used Black study populations that are not representative of the Black population as a whole. Additionally, researchers used incomplete data that excluded participants' sociodemographic characteristics, diet, clinical conditions, and medications, all of which can affect creatinine levels.^{20,21} At the conclusion of the CKD-EPI study, Levey et al. advised that further research would be necessary to improve GFR estimation.²² As a result of limited representation of other minority groups in this study population, these groups were not included in large enough numbers to draw conclusions on racial differences in serum creatinine levels of kidney function.²³

Issues with binary distinction on race

Currently when the Black race coefficient is used in formulas, eGFR calculators only offer two response options: Black or Not Black. These options do not include a designation for mixed race or multiracial individuals and do not account for the existing genetic diversity within the Black population.²⁴ The concept of race is a social construct and an unreliable proxy for genetic difference, therefore not a biological marker or clinical measure.²⁵

Effect of using eGFR

A recent study examined the impact of the race multiplier for the Black population in the CKD-EPI eGFR equation on CKD classification and care delivery by hypothetically removing the Black race coefficient from the eGFR formula. Results found:²⁶

- 16% increase in the total number of Black patients classified as having CKD in this study's registry
- 33.4% of Black participants who were already diagnosed with CKD would have been reclassified to a more severe stage
- 3% or 64 patients were reclassified from an eGFR greater than 20 ml/min to an eGFR equal to or less than 20 ml/min

²⁰ Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. *American Medical Association*. 2019. 322(2):113-114

²¹ Schmidt IM, Waikar SS. Separate and Unequal: Race-Based Algorithms and Implications for Nephrology. *Journal of the American Society of Nephrology*. 2021. 32(3): 529-533.

²² Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. *American Medical Association*. 2019. 322(2):113-114

²³ Delgado C, Baweja M, Rios Burros N, Crews DC, Eneanya ND, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Roberts GV, St. Peter WL, Warfield C, Powe NR. Reassessing the Inclusion of Race in Diagnosing Kidney Diseases: An Interim Report from the NKF-ASN Task Force. *Journal of the American Society of Nephrology*. 2021. 32: 1305- 1317.

²⁴ Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. *American Medical Association*. 2019. 322(2):113-114

²⁵ Vyas DA, Einstein LG, Jones DS. Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms. *The New England Journal of Medicine*. 2020. 383(9): 874-882.

²⁶ Ahmed S, Nutt CT, Eneanya ND, Reese PR, Sivashanker K, Morse M, Sequist T, Mendu ML. Examining the Potential Impact of Race Multiplier Utilization in Estimated Glomerular Filtration Rate Calculation on African-American Care Outcomes. *Journal of General Internal Medicine*. 2020. 36(2):464–71 DOI: 10.1007/s11606-020-06280-5

Overestimated eGFR values resulting from race adjustments have the potential to delay referral for kidney transplantation and the initiation of qualifying waiting time.²⁷ Black patients with CKD have worse outcomes and an increased rate of ESRD when compared with other racial groups.²⁸ They are also less likely to be added to the transplant waiting list and receive a transplant.²⁹ The use of race adjustments in the calculation of eGFR has the potential to exacerbate existing disparities and negatively impact patient outcomes. Timely assessment and intervention is critical for outcomes of CKD patients, as the disease can progress quickly towards kidney failure. Earlier detection of CKD could improve efforts to prevent progression.³⁰

Community efforts

The nephrology community is also currently reconsidering the use of race-based adjustments in clinical algorithms, including eGFR. In July 2020 the issue gained the attention of the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN). These organizations collaborated to form the National Kidney Foundation (NKF) and ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases (the Task Force). The Task Force specifically aims to examine the inclusion of race in estimation of GFR and its implications for diagnosis and subsequent management of patients with, or at risk for, kidney disease.

In March 2021, leaders at both ASN and NKF released a statement asserting that:³¹

Race modifiers should not be included in equations to estimate kidney function and current race-based equations should be replaced by a suitable approach that is accurate, inclusive, and standardized in every laboratory in the United States. Any such approach must not differentially introduce bias, inaccuracy, or inequalities.

In June 2021, the Task Force released an interim report which outlined their work to date and informed the nephrology community that final recommendations regarding estimation of eGFR without the Black race coefficient would be released at a future date.³²

In September 2021, the Task Force released their final recommendations which included the following statement:³³

²⁷ Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. American Medical Association. 2019. 322(2):113-114

²⁸ Ahmed S, Nutt CT, Eneanya ND, Reese PR, Sivashanker K, Morse M, Sequist T, Mendu ML. Examining the Potential Impact of Race Multiplier Utilization in Estimated Glomerular Filtration Rate Calculation on African-American Care Outcomes. Journal of General Internal Medicine. 2020. 36(2):464–71DOI: 10.1007/s11606-020-06280-5

²⁹ Zelnick LR, Leca N, Young B, Bansal N. Association of the Estimated Glomerular Filtration Rate With vs Without a Coefficient for Race with Time to Eligibility for Kidney Transplant. The Journal of the American Medical Association. 2021;4(1):e2034004. doi:10.1001/jamanetworkopen.2020.34004

³⁰ Reese PP, Sumit M, King KL, Williams WW, Potluri VS, Harhay MN, Eneanya ND. Racial disparities in preemptive waitlisting and deceased donor kidney transplantation: Ethics and solutions. The American Journal of Transplant. 2020. 21:958–967. <https://doi.org/10.1111/ajt.16392>

³¹ National Kidney Foundation. (2021, March 9). Removing Race from Estimates of Kidney Function. <https://www.kidney.org/news/removing-race-estimates-kidney-function>

³² Delgado C, Baweja M, Rios Burros N, Crews DC, Eneanya ND, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Roberts GV, St. Peter WL, Warfield C, Powe NR. Reassessing the Inclusion of Race in Diagnosing Kidney Diseases: An Interim Report from the NKF-ASN Task Force. Journal of the American Society of Nephrology. 2021. 32: 1305- 1317.

³³ Ibid.

The Task Force recommends immediate implementation of the CKD-EPI creatinine equation refit without the race variable in all laboratories because the calculation does not include race, it included diversity in its development, its potential adverse consequences do not disproportionately affect any one group, and it is immediately available to all laboratories.

The Task Force also recommended national efforts to increase the availability of cystatin C testing and continued research on GFR estimation that aims to eliminate racial and ethnic disparities.^{34, 35}

Development Process

In November 2020, the United States House of Representatives Ways and Means Committee invited a number of professional organizations, societies, and community stakeholders to comment on a Request for Information (RFI) pertaining to racial bias in clinical tools.³⁶ This communication specifically highlighted the connection between race adjusted eGFR calculations and the racial health inequities in kidney transplantation. This RFI posed questions regarding the organization’s plans for reevaluating the use of race in clinical algorithms and ensuring improved access to transplant for the impacted population.³⁷ Responses from a number of these professional organizations are available on the Ways and Means Committee’s website.³⁸

OPTN Reassess Race in eGFR Calculation Workgroup

In March 2021, the OPTN formed the Reassess Race in eGFR Calculation Workgroup (the Workgroup) to evaluate the use of the Black race coefficient in the eGFR calculation. The Workgroup consists of members from the OPTN Minority Affairs and Kidney Transplantation Committees as well as subject matter experts, including nephrologists, epidemiologists, and patients. The Workgroup first aimed to determine if or what policy should be developed to address the use of the Black race coefficient in eGFR calculations.³⁹ The Workgroup has selected a concentrated scope as it aims to respond to the community’s desire to address this growing initiative in an efficient and timely manner.

³⁴ Inker, L. A., M.D., Eneanya, N. D., Coresh, J., Tighiouart, H., Wang, D., Sang, Y., Crews, D. C., Doria, A., Estrella, M. M., Froissart, M., Grams, M. E., Greene, T., et al., for the Chronic Kidney Disease Epidemiology Collaboration. New Creatinine- and Cystatin C–Based Equations to Estimate GFR without Race. *The New England Journal of Medicine*. 2021. 385:1737-1749. <https://doi.org/10.1056/NEJMoa2102953>

³⁵ Delgado C, Baweja M, Crews DC, Nwamaka ED, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Glenda RV, St. Peter WL, Warfield C, Powe NR. A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease. *Journal of the American Society of Nephrology*. 2021. <https://doi.org/10.1681/ASN.2021070988>

³⁶ Letter to Dr. David Mulligan from the United States House of Representatives Committee on Ways and Means, November 24, 2020.

³⁷ Neal RE, “Clinical Corrections Invitation to Comment” Ways and Means Committee. September 17, 2020. Accessed June 24, 2021 from https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/ClinicalCorrectorsinvitation_final.pdf

³⁸ Ways and Means Committee. “Feedback from Professional Societies and RFI Respondents on the Misuse of Race Within Clinical Care” January 21, 2021. Accessed July 20, 2021 from <https://waysandmeans.house.gov/media-center/press-releases/feedback-professional-societies-and-rfi-respondents-misuse-race-within-0>

³⁹ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, March 1, 2021. Available at <https://optn.transplant.hrsa.gov/>

The Workgroup solicited community input on the following topics:

- Which method of estimating or measuring GFR is your transplant program currently using? Why?
- How would this use of a race-neutral eGFR impact your program?
- What implementation challenges could use of a race-neutral eGFR present for your transplant program?
- What resources could assist in facilitating a smooth transition for your program?
- Do patients support the use of a race-neutral eGFR formula? Why or why not?
- What potential unintended consequences should be considered during this proposal's development?

Summary of Public Comment Feedback⁴⁰

Establish a Race-Neutral eGFR

The vast majority of feedback indicated support for the establishment of an OPTN requirement for race-neutral eGFR calculations. Many supportive responses recognized race as a social construct. These commenters agreed that race should be excluded from methods for calculating eGFR as it is an inaccurate surrogate for genetic ancestry. Responses also point out the imprecise and dichotomous nature of the response options for race on the eGFR calculator: Black or Not Black. Commenters expressed that the removal of race from the eGFR calculation is long overdue.

Some feedback commented on the consequences of utilizing race in eGFR calculations. Respondents expressed that the inclusion of the Black race coefficient could contribute to delayed treatment for CKD, initiation of accrued waiting time, and transplant. They explained that these delays result in overall poorer health and quality of life for Black CKD patients. Responses also refuted the claim that African Americans have more muscle mass and reported the presence of limitations in the studies supporting the inclusion of the Black race coefficient. Feedback indicated that the community is prepared to acknowledge and address the current inequity caused by the Black race coefficient.

Feedback also highlighted the potential positive impacts of establishing an OPTN requirement for race-neutral eGFR calculations. Such impacts include earlier referral for ESRD and initiation of accrued waiting time for Black CKD patients. Commenters expressed the potential for improved access and in turn, expanded lifespans for Black patients. Several respondents announced that their respective programs have already established protocols that require race-neutral eGFR calculations. These institutions reported that the shift to race-neutral formulas was not difficult, but did point out the need to collaborate with their lab partners before any changes could be made.

Feedback on Specific eGFR Requirements

The sponsoring committees received a variety of feedback regarding what specific eGFR requirements should be proposed in January 2022. The majority of commenters supported a policy that allows any eGFR calculation to be used as long as it does not include a race-based coefficient. Among such respondents was the American Society of Transplantation (AST) who commented: "We suggest the Minority Affairs Committee consider a policy that prohibits the use of race-based methods rather than

⁴⁰OPTN Public Comment. Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation, OPTN Minority Affairs and Kidney Transplantation Committees, August 2021 <https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/> (accessed November 12)

mandating a specific method or equation for eGFR⁴¹. Some respondents asked for guidance on which race-neutral formula(s) should be used. A few others expressed the importance of consistency and supported a universal eGFR formula that could be used by every transplant program.

Cystatin C was also mentioned throughout the public comment period. Those who endorsed using cystatin C reported that it can provide additional precision to GFR measurement. Other commenters expressed that this test could be one of the accepted methods for measuring GFR, but not the only method. These respondents explained that cystatin C testing is not universally available, so requiring this test would create access issues for some transplant programs.

Several responses referred to the final recommendations made by the ASN/NKF Task Force.⁴² OPTN Public Comment began in August 2021 and the ASN/NKF Task Force recommendations were released in September prior to OPTN Public Comment closing. Respondents who submitted comments before the release of these recommendations supported the removal of the Black race coefficient, but awaited consensus guidance from the Task Force. Some respondents who submitted comments after the release of this guidance called for alignment with the recommendations to use the CKD-EPI creatinine equation refit without the race variable to calculate eGFR. Feedback also expressed preference for a less prescriptive policy that would require removal of race-based variables when calculating eGFR instead of one specific formula.

Additional Considerations

A call for educational resources

Feedback from the community supported the development of educational resources on any changes made to OPTN policy as a result of the proposal. Supporters suggested education geared towards patients, referring nephrologists, and transplant programs. Commenters recognized the importance of informing the CKD patient population of the impact a shift towards race-neutral eGFR calculations could have on their eGFR values. Responses also highlighted the referring nephrology community as a target audience for education on changes. Additionally, respondents expressed that transition resources should be developed for transplant programs to train coordinators and inform staff on methods for calculating race-neutral eGFRs.

Potential consequences for consideration

Some commenters provided feedback on potential consequences of establishing an OPTN requirement for race-neutral eGFR calculations. One such consequence was that removal of the Black race coefficient from eGFR calculations could unintentionally reduce the number of qualified Black living donors. Some commenters expressed concern that potential Black living donors may be inappropriately excluded from qualifying for donation and that this might exacerbate existing disparities. Other responses indicated concern surrounding the impacts of underestimated eGFRs for Black patients. These concerns included over diagnosis of CKD, premature dialysis initiation, and promotion of unnecessary

⁴¹ OPTN Public Comment. Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation, OPTN Minority Affairs and Kidney Transplantation Committees, August 2021 <https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/> (accessed November 12)

⁴² Delgado C, Baweja M, Crews DC, Nwamaka ED, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Glenda RV, St. Peter WL, Warfield C, Powe NR. A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease. *Journal of the American Society of Nephrology*. 2021. <https://doi.org/10.1681/ASN.2021070988>

transplants. A few respondents asked about the possibility of modifying waiting time for Black kidney candidates currently listed using an eGFR calculation that includes race who would have qualified to accrue waiting time at an earlier date if an eGFR calculation that excludes race was used.

Purpose

This proposal's purpose is to prohibit the use of eGFR calculations that include a race- based variable in OPTN policy. This proposal defines GFR within *OPTN Policy 1.2: Definitions* so that any eGFR calculation that does not include a race- based variable may be used. This requirement for race- neutral calculations intends to increase equity in access to transplantation for Black kidney candidates by more accurately estimating their GFR values. If the Black race coefficient is prohibited from use in eGFR calculations within OPTN policy, Black kidney candidates' eGFR values will be more reflective of their actual kidney function.

Overview of Proposal

The Minority Affairs and Kidney Transplantation Committees propose updating OPTN policy to require eGFR calculations be race- neutral. This section of the paper describes the Workgroup's policy development process, how race- neutral eGFRs would impact OPTN policy, and consideration of potential unintended consequences.

Developing a Policy Solution

The Workgroup considered two policy solutions, selecting one universal eGFR formula or allowing any eGFR formula be used as long as it does not contain a race-based variable. They discussed that the selection of one universal formula would better align with the new ASN/NFK recommendations, but may be overly prescriptive at this time.⁴³ The Workgroup also considered the rapidly evolving nephrology field and ongoing advancements regarding the estimation of kidney function. After learning that additional and potentially more accurate race- neutral eGFR calculations are already under development, the Workgroup determined that they would recommend the less prescriptive of the two policy solutions.^{44,45} As additional advancements are made in this field, the Sponsoring Committees will continue to assess whether the selected policy solution remains appropriate or if one specific eGFR formula should be universally required.

One of the Task Force's final recommendations calls for:⁴⁶

⁴³ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, October 5, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁴⁴ Delgado C, Baweja M, Crews DC, Nwamaka ED, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Glenda RV, St. Peter WL, Warfield C, Powe NR. A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease. *Journal of the American Society of Nephrology*. 2021. <https://doi.org/10.1681/ASN.2021070988>

⁴⁵ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, October 5, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁴⁶ Delgado C, Baweja M, Crews DC, Nwamaka ED, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Glenda RV, St. Peter WL, Warfield C, Powe NR. A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease. *Journal of the American Society of Nephrology*. 2021. <https://doi.org/10.1681/ASN.2021070988>

Research on GFR estimation with new endogenous filtration markers and on interventions to eliminate race and ethnic disparities should be encouraged and funded. An investment in science is needed for newer approaches that generate accurate, unbiased, and precise GFR measurement and estimation without the inclusion of race, and that promote health equity and do not generate disparate care.

Proposing a less prescriptive policy which only requires that a race variable not be used places OPTN members in position to utilize the most modern race- neutral eGFR calculations as research on the topic continues to advance.⁴⁷

Race- Neutral eGFR Calculations in OPTN Policy

Defining GFR

The Workgroup proposes adding the following definition to *OPTN Policy 1.2: Definitions*:

Glomerular Filtration Rate (GFR): A measure of filtering capacity of the kidneys. GFR can be measured directly or estimated (eGFR) using various formulae. Formulae used to calculate an eGFR must not use a race- based variable.

The proposed definition prohibits use of formulae used to calculate eGFR that include a race- based variable and would apply throughout OPTN policy, affecting all policies that include eGFR. To comply with this proposed policy, formulae used to estimate GFR are required to be race- neutral. Several clerical language changes are proposed in the affected policies to align with the addition of the GFR definition.

Impact on Waiting Time and Prioritization Policies

The addition of GFR to *OPTN Policy 1.2: Definitions* would require that race- neutral eGFR calculations are used for the following policies regarding waiting time and prioritization:

- Policy 3.6.B.i: Non-function of a Transplanted Kidney
- Policy 8.4. A: Waiting Time for Candidates Registered at Age 18 Years or Older
- Policy 8.5. G: Prioritization for Liver Recipients on the Kidney Waiting List

Each of these OPTN policies use eGFR thresholds as qualifying criteria. The proposed change to OPTN policy intends to increase GFR estimation accuracy and access to transplantation for Black kidney candidates, as more of these candidates should meet the qualifying thresholds in a timelier manner.

Impact on OPTN Policy 9.5. H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

One of the three qualifying criteria in *OPTN Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions* currently includes a requirement for an eGFR of six variable MDRD6 or GFR measured by iothalamate or iohexol, less than or equal to 25 mL/min on 2 occasions at least 42 days apart. The MDRD6 eGFR formula includes a race- based variable. In order to align with this proposal for

⁴⁷ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, October 5, 2021. Available at <https://optn.transplant.hrsa.gov/>

race-neutral eGFR calculations, MDRD6 would be removed so that any eGFR calculation may be used, as long as it does not include a race- based variable. The OPTN Liver and Intestinal Organ Transplantation Committee was consulted and agreed on this change. The sponsoring committees determined language stating that measured GFR should be done with iothalamate or iohexol should be removed because it is unnecessary.

Considering Potential Consequences

Decrease in qualifying potential Black living donors

The Workgroup acknowledges the potential for unintended consequences as a result of this policy change. The first and most frequently expressed concern was that potential Black living donors may be inappropriately excluded from qualifying for donation if the Black race coefficient was removed from their eGFRs.⁴⁸ The Workgroup understands this concern as living kidney donation is considered optimal treatment for candidates with CKD and is linked to improved patient outcomes.⁴⁹ Historically, the Black population has had limited access to living donor organs. In 2019, the Black population represented 31.5% of the kidney transplant waiting list but only 13.1% of living donor kidney transplant recipients. Conversely, White patients represented 37.9 % of the transplant waiting list and 63.9% of living donor kidney transplant recipients.⁵⁰

Workgroup members noted that measurement of GFR by isotopic method or a creatinine clearance calculated from a 24-hour urine collection, not an estimation of GFR, is the listed requirement in *OPTN Policy 14.4.B: Additional Requirements for the Medical Evaluation of Living Kidney Donors*.^{51, 73} Even so, the Workgroup acknowledged that some transplant programs may use eGFR to screen potential living kidney donors. In this case higher eGFRs are associated with decreased risk to potential living donors and lower eGFRs are associated with increased risk to potential living donors.⁵² A prospective Black living kidney donor whose status changes from qualifying to not qualifying based upon the use of a race-neutral eGFR calculation should not be considered “inappropriately excluded”, as their previously qualifying eGFR value was likely near the low end of the program’s acceptable risk threshold.⁵³ For these reasons, the sponsoring committees find accurate estimation of GFR crucial for the safety of potential Black living kidney donors.

⁴⁸ Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation, OPTN Minority Affairs and Kidney Transplantation Committees, August 2021, https://optn.transplant.hrsa.gov/media/4782/2021august_-reassess-race-in-egfr_request-for-feedback.pdf (accessed November 12, 2021)

⁴⁹ Kuppachi, S., Norman, S. P., Lentine, K. L., Axelrod, D. A. Using race to estimate glomerular filtration and its impact in kidney transplantation. *Clinical Transplant*. 2020. <https://doi.org/10/1111/ctr.14136>

⁵⁰ Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). *OPTN/SRTR 2019 Annual Data Report*. Rockville: Department of Health and Human Services, Health Resources and Services Administration; 2021. Accessed September 29, 2021. <https://srtr.transplant.hrsa.gov>

⁵¹ OPTN Public Comment. Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation, OPTN Minority Affairs and Kidney Transplantation Committees, August 2021 <https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/> (accessed November 12)

⁵² OPTN Policy 14.4.B: Additional Requirements for the Medical Evaluation of Living Kidney Donors

⁵³ OPTN Public Comment. Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation, OPTN Minority Affairs and Kidney Transplantation Committees, August 2021 <https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/> (accessed November 12)

Underestimation of GFR

Some community members voiced concern that the removal of the race coefficient could underestimate Black patient's eGFRs. Impacts of underestimation could include over diagnosis of CKD, premature dialysis initiation, and promotion of unnecessary transplants.⁵⁴ While research has shown that the removal of the Black race coefficient may reclassify Black patients to a more severe stage of CKD, the Workgroup noted that this population has higher rates of end-stage kidney disease and death due to kidney failure when compared with the overall population.^{55, 56} Because the inclusion of the Black race coefficient overestimates Black patients' eGFR and does not accurately recognize the severity of their illness, Black patients may not receive timely CKD intervention. The Workgroup discussed that the removal of the Black race coefficient could improve timing of CKD treatment, prevent disease progression, and contribute to better patient outcomes.⁵⁷

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,”⁵⁸ and the OPTN Final Rule, which states the OPTN shall develop "Policies for the equitable allocation of cadaveric organs in accordance with §121.8."⁵⁹ This proposal impacts allocation of organs because using a Black race coefficient overestimates eGFR values, which can delay the accrual of wait time, which could impact a candidate's 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.”⁶⁰ This proposal is:

⁵⁴ OPTN Public Comment. Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation, OPTN Minority Affairs and Kidney Transplantation Committees, August 2021 <https://optn.transplant.hrsa.gov/governance/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/> (accessed November 12)

⁵⁵ Ahmed S, Nutt CT, Eneanya ND, Reese PR, Sivashanker K, Morse M, Sequist T, Mendu ML. Examining the Potential Impact of Race Multiplier Utilization in Estimated Glomerular Filtration Rate Calculation on African-American Care Outcomes. *Journal of General Internal Medicine*. 2020. 36(2):464–71DOI: 10.1007/s11606-020-06280-5

⁵⁶ Vyas DA, Einstein LG, Jones DS. Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms. *The New England Journal of Medicine*. 2020. 383(9): 874-882.

⁵⁷ Ibid.

⁵⁸ 42 U.S.C. §274(b)(2)(B)

⁵⁹ 42 CFR §121.4(a) (1).

⁶⁰ 42 C.F.R. §121.8(a)

- **Is based on sound medical judgment**⁶¹. The proposed changes to OPTN policy are supported by data and literature showing that inclusion of the Black race coefficient in eGFR calculations overestimates Black kidney candidates eGFR values.⁶² The data and literature show that if race-neutral eGFR calculations are required the severity of Black kidney candidates' illness will be recognized and support timely referral for kidney transplantation and the initiation of qualifying waiting time.⁶³
- **Seeks to achieve the best use of donated organs**⁶⁴ by ensuring organs are allocated and transplanted according to medical urgency. Requiring race- neutral eGFR calculations will more accurately estimate Black kidney candidate's kidney function and therefore provide a more accurate assessment of their medical urgency.
- **Is designed to...promote patient access to transplantation**⁶⁵ by giving similarly situated candidates equitable opportunities to receive an organ offer. Requiring race- neutral eGFR calculations will allow kidney candidates with similar degrees of medical urgency to have equal opportunities to receive an organ offer, independent of candidates' race.
- **This proposal is not based on the candidate's place of residence or place of listing.**

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 transplants
- Is designed to avoid wasting organs
- Promotes the efficient management of organ placement

Implementation Considerations

Member and OPTN Operations

Operations affecting the OPTN

The OPTN will implement the proposed changes to policy in the UNetSM system. There will be limited changes to the WaitlistSM application, including modifications to labels on the kidney and kidney-pancreas candidate records as well as the simultaneous liver- kidney section of the liver candidate record. Additionally, appropriate modifications will be made to update MELD/PELD exception forms with GFR references.

Operations affecting Transplant Hospitals

This proposal is anticipated to affect the operations of transplant hospitals. Upon implementation, transplant hospitals will not be permitted to use eGFR calculations that include race for purposes of the OPTN. Transplant hospitals that have not already transitioned to the use of race-neutral eGFR calculations will need to do so at this time. The transition process could include program- wide notification of this policy change and training for staff. Transplant hospitals may also have to update

⁶¹ 42 CFR §121.8(a) (1).

⁶² Ahmed S, Nutt CT, Eneanya ND, Reese PR, Sivashanker K, Morse M, Sequist T, Mendu ML. Examining the Potential Impact of Race Multiplier Utilization in Estimated Glomerular Filtration Rate Calculation on African-American Care Outcomes. *Journal of Should I General Internal Medicine*. 2020. 36(2):464–71DOI: 10.1007/s11606-020-06280-5

⁶³ *ibid.*

⁶⁴ 42 CFR §121.8(a)(2).

⁶⁵ *Id.*

their EMRs and work with lab partners to modify eGFR calculation and reporting for purposes of the OPTN.

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.”⁶⁶ If approved, this policy could improve access to transplantation for Black kidney candidates by appropriately prioritizing them amongst all other candidates awaiting kidney transplantation.

The Sponsoring 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 Committee did not identify any populations that may be treated “less favorably than they would have been treated under the previous policies” if these proposed policies are approved by the Board of Directors, because this policy change aims to correct an existing disadvantage to access for Black patients.⁶⁷ Rather, the sponsoring committees are considering developing a pathway for transplant centers to modify waiting time for kidney candidates who could have begun accruing waiting time at an earlier date if a race-neutral eGFR calculation was used.

Projected Fiscal Impact

This proposal is expected to have a fiscal impact on the OPTN, and does not have a fiscal impact on organ procurement organizations or histocompatibility laboratories, but there could be a fiscal impact on transplant hospitals.

Projected Impact on the OPTN

This project is expected to have a small impact on the OPTN, primarily related to the changes associated with the kidney, kidney-pancreas, and simultaneous liver- kidney candidate forms in addition to appropriate updates to the MELD/PELD exception forms.

Projected Impact on Transplant Hospitals

Transplant programs could incur minor operational costs, but the extent of this cost depends upon which race- neutral formula the transplant program elects to use. Additionally, there could be costs

⁶⁶ 42 C.F.R. § 121.8(d).

⁶⁷ See Reassess Race in eGFR Calculation Workgroup Meeting Summary, November 1, 2021. Available at <https://optn.transplant.hrsa.gov/>

associated with staff training and new education process efforts, as well as changes to contractual agreements if the transplant hospital is outsourcing eGFR testing. There could be an ongoing fiscal impact for transplant hospitals due to the increased number of candidates that could be listed after the proposal is implemented.

Projected Impact on Histocompatibility Laboratories

No Impact.

Projected Impact on Organ Procurement Organizations

No Impact.

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.”⁶⁸

This proposal will not change current routine monitoring of OPTN members. The OPTN may review any data entered in UNetSM, and members must provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”⁶⁹

Committee considers the number of Black kidney candidates listed pre-dialysis, the number of kidney transplants to Black candidates, and the amount of time waiting until transplant for Black kidney candidates the key metrics to assess the outcome of the proposed change to eGFR requirements. All metrics will be compared pre- to post-implementation and will be provided both overall and stratified by ethnicity, with particular attention paid to the impact on Black candidates.

Metrics to be evaluated include:

- Count and percent of Black kidney candidates listed pre-dialysis
- Number of kidney transplants to Black candidates, broken out by transplants performed pre-dialysis versus post-dialysis
- eGFR at listing for Black kidney candidates qualifying by eGFR
- Waiting list mortality for Black kidney candidates
- Time waiting from listing until transplant for Black kidney candidates

⁶⁸ 42 CFR §121.8(a)(7).

⁶⁹ 42 CFR §121.8(a)(6).

These metrics will be reviewed at approximately six months, one year, and two years post-implementation. Waiting list mortality and time waiting to transplant will be provided only at one and two years post-implementation.

Conclusion

Current OPTN policy is not prescriptive as to which eGFR calculation must be used. This proposal's purpose is to prohibit the use of eGFR calculations that include a race-based variable. This policy change intends to increase equity in access to transplantation for Black kidney candidates by more accurately estimating their GFR values. If the OPTN requires race-neutral eGFR calculations are used, Black kidney candidates' eGFR values will be more reflective of their actual kidney function.

Community Feedback

- Do community members agree with the sponsoring committees' proposed policy solution? Why or why not.
- If approved, what changes would transplant programs need to make to align with this policy?
- What kind of educational resources would assist in facilitating a smooth transition for your program?
- What impact would this proposal have on patients?
- Should the OPTN considering developing a pathway for transplant centers to modify waiting time for kidney candidates who could have begun accruing waiting time at an earlier date if a race-neutral eGFR calculation was used? If yes, how could this be done?
- Do community members believe that the potential positive impact of this proposal outweighs the potential unintended consequences? Why or why not?

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 1.2 Definitions

2 The definitions that follow are used to define terms specific to the OPTN Policies.

3

4 **Glomerular Filtration Rate (GFR)**

5 A measure of filtering capacity of the kidneys. GFR can be measured directly or estimated (eGFR) using
6 various formulae. Formulae used to calculate an eGFR must not use a race- based variable.

7

8 **3.6.B.i Non-function of a Transplanted Kidney**

9 Immediate and permanent non-function of a transplanted kidney is defined as *either*:

- 10 • Kidney graft removal within the first 90 days of transplant documented by an
11 operative report of the removal of the transplanted kidney.
- 12 • Kidney graft failure within the first 90 days of transplant with documentation that
13 the candidate is either on dialysis or has measured or estimated creatinine
14 clearance (CrCl) or ~~calculated~~ glomerular filtration rate (GFR) less than or equal to
15 20 mL/min within 90 days after the candidate's kidney transplant.

16 Kidney waiting time will be reinstated when the OPTN receives a completed *Renal Waiting Time*
17 *Reinstatement Form* and the supporting documentation required above. The Estimated Post Transplant
18 Survival (EPTS) score will also be calculated without interruption. The OPTN will send a notice of waiting
19 time reinstatement to the transplant hospital involved.

20 **8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older**

21 If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney,
22 then the candidate's waiting time is based on the earliest of the following:

23

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

31

32 **8.5.G Prioritization for Liver Recipients on the Kidney Waiting List**

33 If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the
34 same deceased donor, the candidate will be classified as a prior liver recipient. This classification
35 gives priority to a kidney candidate if *both* of the following criteria are met:

36

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant date, at least *one* of the following criteria is met:
 - The candidate has a measured or ~~calculated~~ estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
 - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a liver recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*. If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a liver and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*

9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the candidate's transplant hospital submits evidence of all of the following:

1. The liver candidate is registered on the waiting list for a kidney transplant at that transplant hospital.
2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis.
3. ~~Estimated~~ Measured or estimated glomerular filtration rate (GFR) ~~by six variable Modification of Diet in Renal Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or iohexol,~~ is less than or equal to 25 mL/min on 2 occasions at least 42 days apart.

1 **13.7.G OPTN KPD Waiting Time Reinstatement**

2 KPD waiting time begins on the day the candidate’s transplant hospital registers the candidate in
3 the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is
4 registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active
5 and inactive status in the OPTN KPD program.

6 The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if
7 the OPTN KPD candidate experiences immediate and permanent non-function of any
8 transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program with
9 another living donor. Immediate and permanent non-function of a transplanted kidney is
10 defined as *either*:

- 11 1. Kidney graft removal within the first 90 days of transplant documented by a report of the
12 removal of the transplanted kidney.
- 13 2. Kidney graft failure within the first 90 days of transplant with documentation that the
14 candidate is either on dialysis or has measured or estimated creatinine clearance (CrCl) or
15 ~~calculated~~ glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days of
16 the kidney transplant.

17
18