

Public Comment Proposal

Monitor Ongoing eGFR Modification Policy Requirements

OPTN Minority Affairs Committee

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Monitor Ongoing eGFR Modification Policy Requirements

<i>Affected Policies:</i>	<i>3.7.D Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations</i>
<i>Sponsoring Committee:</i>	<i>Minority Affairs</i>
<i>Public Comment Period:</i>	<i>January 21, 2025- March 19, 2025</i>

Executive Summary

The OPTN Minority Affairs Committee (MAC) submits the *Monitor Ongoing eGFR Modification Policy Requirements* proposal which updates ongoing policy requirements in *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*.¹

As of January 4, 2024, ongoing requirements include:²

- Continue to notify all newly registered kidney candidates of the requirements of the transplant program according to the policy
- Continue to assess all newly registered kidney candidates to determine eligibility
- Submit completed waiting time modification requests to the OPTN

The MAC proposes three areas for which programs must have specific, written protocols and thorough documentation to address the requirements of OPTN Policy 3.7.D:³

- Confirming candidate race
- Fulfilling notification requirements
- Seeking supporting documentation of eligibility, including, at a minimum, what sources will be reviewed

Additionally, the MAC aims to update the requirements of this policy to more explicitly include:⁴

- *3.7.D.i. Notification Requirement*
 - Requirement that transplant programs provide notifications to all kidney candidates of their eligibility for a waiting time modification based on race inclusive eGFR calculations
 - Requirement that transplant programs provide notifications to kidney candidates who had an eGFR waiting time modification submitted on their behalf of the outcomes of those waiting time modifications
 - Application of these proposed notification requirements retrospectively to all candidates registered on or after January 4, 2024
- *3.7.D.ii Determination of Eligible Candidates*

¹ OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations.

² Waiting time modifications for candidates affected by race-inclusive eGFR calculations Toolkit, OPTN, Accessed November 17, 2024, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/waiting-time-modifications-for-candidates-affected-by-race-inclusive-egfr-calculations/>.

³ See Minority Affairs Committee meeting summary, November 18, 2024. Available at https://optn.transplant.hrsa.gov/media/44bmvorc/20241118_mac_summary.pdf.

⁴ Ibid.

- Additional language to support the existing requirement that all kidney candidates must be assessed for eligibility
- 3.7.D.iv Reporting Requirements for Kidney Transplant Programs
 - The removal of outdated attestation language

The OPTN Membership and Professional Standards Committee (MPSC) referred *Monitor Ongoing eGFR Modification Policy Requirements* to the MAC upon identifying an opportunity to provide additional direction for transplant programs. These updates aim to better ensure that transplant programs are properly evaluating all candidates for GFR waiting time modifications.⁵

Purpose

The purpose of this proposal is to update and enhance ongoing policy requirements in *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*.

Background

Prior OPTN Policies related to eGFR

On July 27, 2022, the OPTN implemented *Establish OPTN Requirement for Race Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations*, which prospectively prohibited transplant programs from using race-inclusive eGFR calculations for purposes of the OPTN.⁶

On January 5, 2023, the OPTN implemented *Modify Waiting Time for Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations*, which required all kidney transplant programs to meet the following requirements by January 3, 2024:⁷

- Notify all registered kidney candidates that programs are responsible for reviewing their waitlist for eligible candidates
- Assess their entire kidney waiting list for eligible candidates
- Submit completed requests for waiting time modification for all eligible candidates to the OPTN
- Submit attestation documentation to the OPTN of the program's compliance with the above requirements

As of January 4, 2024, ongoing requirements include:⁸

- Continue to notify all newly registered kidney candidates of the requirements of the transplant program according to the policy
- Continue to assess all newly registered kidney candidates to determine eligibility

⁵ See Minority Affairs Committee meeting summary, April 4, 2024. Available at https://optn.transplant.hrsa.gov/media/wyndlabg/20240404_mac_summary.pdf.

⁶ "Establish OPTN Requirement for Race Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations", OPTN, Policy Notice, accessed November 17, 2024, https://optn.transplant.hrsa.gov/media/xn3nhhjr/policy-notice_establish-optn-req-for-race-neutral-egfr-calccls_mac.pdf.

⁷ "Modify Waiting Time for Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations", OPTN, Policy Notice, accessed November 17, 2024, https://optn.transplant.hrsa.gov/media/nislhg4/policy-notice_egfrwtmods_mac_ki.pdf.

⁸ Waiting time modifications for candidates affected by race-inclusive eGFR calculations Toolkit, OPTN, Accessed November 17, 2024, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/waiting-time-modifications-for-candidates-affected-by-race-inclusive-egfr-calculations/>.

- Submit completed waiting time modification requests to the OPTN

Project Referral from the Membership and Professional Standards Committee

The MPSC referred this project to the MAC with the recommendation that policy be updated to require every transplant program to maintain a written protocol that outlines their process for evaluating kidney candidates for eGFR waiting time modifications, after observing that transplant hospitals implemented the policy requirements in various ways. To develop this proposal, the MAC collaborated with a variety of stakeholders, including members from the Kidney Committee, Transplant Coordinators Committee (TCC), Transplant Administrators Committee (TAC), and MPSC.⁹

Overview of Proposal

This proposal would require every transplant program to document, in writing, protocols that include processes for meeting the requirements of OPTN Policy 3.7.D, including three specific areas:¹⁰

- Confirming candidate race
- Fulfilling notification requirements
- Seeking supporting documentation, including at a minimum, what sources will be reviewed

Additionally, the MAC aims to update the requirements of this policy to more explicitly include:¹¹

- *3.7.D.i. Notification Requirement*
 - Requirement that transplant programs provide notifications to all kidney candidates of their eligibility for a waiting time modification based on race inclusive eGFR calculations
 - Requirement that transplant programs provide notifications to kidney candidates who had an eGFR waiting time modification submitted on their behalf of the outcomes of those waiting time modifications
 - Application of these proposed notification requirements retrospectively to all candidates registered on or after January 4, 2024
- *3.7.D.ii Determination of Eligible Candidates*
 - Additional language to support the existing requirement that all kidney candidates must be assessed for eligibility
- *3.7.D.iv Reporting Requirements for Kidney Transplant Programs*
 - The removal of outdated attestation language

Written Protocols

The following proposed requirements will seek to provide more objective requirements for transplant programs related to OPTN Policy 3.7.D, as well as standardize the process for transplant programs to document implementation of the requirements.

⁹ See Minority Affairs Committee meeting summary, May 20, 2024. Available at https://optn.transplant.hrsa.gov/media/mq5feqrp/20240520_mac-meeting-summary.pdf.

¹⁰ See Minority Affairs Committee meeting summary, November 18, 2024. Available at https://optn.transplant.hrsa.gov/media/44bmvorc/20241118_mac_summary.pdf.

¹¹ Ibid.

Confirming candidate race

The MAC proposes that programs must document, in writing, protocols and maintain documentation for confirming each candidate's race upon registration.¹² Candidate race is the first criterion that must be met when determining eligibility for an eGFR waiting time modification. Candidates that are registered to the OPTN Waiting List as Black or African American meet that criterion, while candidates of other races do not. For example, a candidate who is registered to the OPTN Waiting List as White would not be evaluated for eGFR waiting time modification eligibility. Candidate race must be recorded correctly in the OPTN Computer System, so all candidates who may qualify for an eGFR waiting time modification will have the opportunity to benefit. If programs have a process for confirming candidate race, it will enhance programs' ability to complete the policy requirements for all eligible candidates. The MAC proposes this as a prospective requirement that would be applied to candidates registered on or after the date this policy proposal is implemented. The MAC discussed examples of how a program may confirm candidate race and keep documentation in the candidates' medical record. Examples may include but are not limited to a completed protocol checklist, Electronic Medical Record (EMR) notes, self-identification forms, or verification form.¹³

Fulfilling notification requirements

The MAC proposes explicitly requiring that programs must document in writing a protocol for fulfilling all existing and updated notification requirements and retain documentation for all candidates in individual medical records. During discussions, the MAC highlighted that while a program's protocol for notifying candidates could be to send the notifications as letters, the requirement could also be fulfilled through other means of communication, such as, but not limited to in-person conversations, phone calls, email, etc.¹⁴ Acceptable documentation for fulfilling notification requirements may include but are not limited to a completed protocol checklist, copies of letters or electronic communications sent to the candidates, or an EMR note confirming an in-person or phone conversation. Proposed updates to notification requirements are explained in the next section of this paper.

Seeking supporting documentation, including at a minimum, what sources will be reviewed

The MAC proposes that programs document, in writing, their protocol for what sources will be reviewed in determining a candidate's eligibility, and to maintain documentation supporting their search for documentation. The policy already requires transplant programs to review documentation to determine eligibility, but this proposed update to policy would require the program to explicitly document, in their written protocol, how they seek that documentation, to bring more consistency and structure to the process for seeking documentation. For example, a program's protocol might include their EMR, internal lab, referring dialysis centers, and external labs. Then, when assessing a candidate for an eGFR waiting time modification, they would review the listed sources and document in the candidates' medical record if any supporting documentation was or was not found. The MAC considered providing a standardized list of sources for programs to check, but determined this too prescriptive as sources vary between programs, depending upon size, availability of resources, and the EMR systems.¹⁵ Members also agreed

¹² See Minority Affairs Committee meeting summary, July 15, 2024. Available at https://optn.transplant.hrsa.gov/media/e5snyuk/20240715_mac_summary.pdf.

¹³ See Minority Affairs Committee meeting summary, November 18, 2024. Available at See Minority Affairs Committee meeting summary, November 18, 2024. Available at https://optn.transplant.hrsa.gov/media/44bmvorc/20241118_mac_summary.pdf.

¹⁴ See Minority Affairs Committee meeting summary, August 19, 2024. Available at https://optn.transplant.hrsa.gov/media/2m0nfesh/20240819_mac_summary.pdf.

¹⁵ See Minority Affairs Committee meeting summary, September 30, 2024. Available at https://optn.transplant.hrsa.gov/media/acwf5iug/20240930_mac_summary.pdf.

that programs listing their own sources would help the OPTN understand the types of resources to which each program has access.¹⁶ The MAC proposes this as a prospective requirement that would be applied to candidates registered on or after the date this policy proposal is implemented.

Updates to Policy 3.7.D

The MAC proposes the following updates to existing requirements outlined in OPTN Policy 3.7.D.

3.7.D.i. Notification Requirement

Currently, OPTN Policy 3.7.D requires transplant programs to notify all kidney candidates registered at their program of the policy requirements of the program, including that all kidney candidates will be assessed for eligibility, but does not explicitly require programs to notify candidates of their eligibility determination.

Update notification requirements

As the MAC considered the written protocol, they discussed ways to enhance the current requirements of *3.7.D.i. Notification Requirement*. Stakeholder committees described effective practices of transplant programs for notifying candidates, including educating candidates on the policy, making candidates aware of whether they will have an eGFR modification submitted to the OPTN on their behalf, and informing candidates if the OPTN approved the modification.¹⁷ The MAC found this practice more transparent, as it keeps candidates better informed on the status of their waiting time.¹⁸ The MAC determined that to support this practice, it would be best to explicitly require such in policy. To better ensure clear direction to kidney transplant programs and more information to candidates, the MAC proposes specific and defined notification requirements.¹⁹

The MAC proposes that transplant programs provide the following information to kidney candidates:

- Education notification: All kidney candidates must be informed of OPTN Policy 3.7.D upon registration. Currently required for all kidney candidates.
- Eligibility notification: All kidney candidates must be informed if supporting documentation was/was not found and if an eGFR modification form was/was not submitted on their behalf. Proposed requirement for all kidney candidates.
- Outcome notification: Kidney candidates must be notified whether the OPTN accepted the submission and modified their time. Proposed requirement for candidates that had an eGFR waiting time form submitted on their behalf.

It is important to note that notification requirements as proposed are not prescriptive regarding timing. Notifications may be communicated at separate points in time or at the same time as long as requirements for each notification as defined above are met.²⁰ In most cases, there are opportunities to combine required information into either one or two communications to kidney candidates, thus

¹⁶ See Minority Affairs Committee meeting summary, July 15, 2024. Available at https://optn.transplant.hrsa.gov/media/e5snyuk/20240715_mac_summary.pdf.

¹⁷ See Minority Affairs Committee meeting summary, July 15, 2024. Available at https://optn.transplant.hrsa.gov/media/e5snyuk/20240715_mac_summary.pdf.

¹⁸ Ibid.

¹⁹ See Minority Affairs Committee meeting summary, August 19, 2024. Available at https://optn.transplant.hrsa.gov/media/2m0nfesh/20240819_mac_summary.pdf.

²⁰ See Minority Affairs Committee meeting summary, August 19, 2024. Available at https://optn.transplant.hrsa.gov/media/2m0nfesh/20240819_mac_summary.pdf.

reducing administrative burden on transplant programs, but the proposed eligibility notification requires the program to complete the search for supporting documentation prior to notification delivery. Collaborating committee members described one effective practice their programs use is to seek supporting documentation and submit modifications immediately after registering the candidate, so any approved modifications can be applied to the candidate's waiting time as soon as possible.²¹ The proposed notification structure aims to encourage programs to seek documentation and submit any eGFR modifications for candidates immediately after registration. Candidates that have a waiting time modification submitted on their behalf are required to receive an outcome notification informing them whether the OPTN accepted the submission and adjusted their waiting time. The MAC is actively seeking feedback from the community on the proposed updated notification requirements, including if the search for supporting documentation search must be completed prior to delivery of the eligibility notification.

The MAC and stakeholder committees discussed that while sending letters is a common practice to fulfill the notification requirements, they also minimize burden by utilizing phone calls, EMR communications, and any scheduled face-to-face meetings to provide this type of information to kidney candidates.²²

Candidates registered on or after January 4, 2024

In addition to notifying newly registered candidates, the MAC also proposes a requirement for transplant programs to retrospectively notify all candidates registered on or after January 4, 2024, of the proposed eligibility and outcome notification requirements, as well as document this notification according to the updated policy language and written protocols. Though current policy requires all candidates to be assessed for eligibility of a modification, some programs may not be notifying candidates of their eligibility or outcome of their modification application. MAC members, including patient representatives, emphasized the importance of transparency in notifying every candidate of their eligibility and/or outcome. Because programs were required to attest to notifying candidates of their eligibility for all candidates prior to January 3, 2024, the MAC chose January 4, 2024, so that all registered kidney candidates receive the same information and that this should not differ based on when a candidate was registered on the waiting list.²³ Stakeholder committee representatives noted concern about this proposed recommendation, as it would be burdensome for programs. They elaborated that they did not think it would be fair to require programs to comply with retrospective policy changes. These stakeholder committee members added that retroactive policy requirements could divert resources away from current priorities and could cause disruption to transplant programs' operations.²⁴ The MAC is actively seeking feedback from the community on whether the policy requirements to notify candidates of their eligibility for a wait time modification according to 3.7.D and the outcome of any such modification application should apply retroactively or proactively.²⁵

²¹ See Minority Affairs Committee meeting summary, July 15, 2024. Available at https://optn.transplant.hrsa.gov/media/e5snyuk/20240715_mac_summary.pdf.

²² See Minority Affairs Committee meeting summary, August 19, 2024. Available at https://optn.transplant.hrsa.gov/media/2m0nfesh/20240819_mac_summary.pdf.

²³ See Minority Affairs Committee meeting summary, November 18, 2024. Available at https://optn.transplant.hrsa.gov/media/44bmvorc/20241118_mac_summary.pdf.

²⁴ See Minority Affairs Committee meeting summary, November 18, 2024. Available at https://optn.transplant.hrsa.gov/media/44bmvorc/20241118_mac_summary.pdf.

²⁵ Ibid.

3.7.D.ii Determination of Eligible Candidates

The MAC sought to add language to support the existing requirement that all kidney candidates must be assessed for eligibility. Although the current language in OPTN Policy 3.7.D states that *all* kidney candidates must be assessed for eligibility, the MAC proposes additional language to clearly state that multi-organ transplant (MOT) candidates and inactive candidates are included within the scope of eligibility.²⁶ This aims to explicitly require that every kidney candidate registered to the OPTN Waiting List is assessed for eGFR waiting time modification eligibility.

3.7.D.iv Reporting Requirements for Kidney Transplant Programs

Upon implementation of *Modify Waiting Time for Candidates Affected by Race Inclusive eGFR Calculations* on January 5, 2023, programs had until January 3, 2024, to meet the policy's requirements. Current language in OPTN Policy 3.7.D requires kidney transplant programs to submit documentation to the OPTN attesting that they have assessed their waiting lists, submitted modifications and supporting documentation, and notified candidates.²⁷ This attestation requirement served as demonstration of compliance from programs to the OPTN. The MAC supports removing this language, as it is no longer applicable and ongoing compliance will be monitored through other means.²⁸

NOTA and Final Rule Analysis

The OPTN Minority Affairs Committee submits 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,” and the OPTN Final Rule, which states the OPTN “shall 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”²⁹ and “conduct ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies”.³⁰ This proposal standardizes practices of how transplant programs are implementing the requirements of OPTN Policy 3.7.D, enhancing transplant programs understanding of the policy requirements and the OPTN's approach to monitoring OPTN Policy 3.7.D.

Implementation Considerations

Member and OPTN Operations

This proposal is expected to affect the operations of transplant hospitals and the OPTN but is not expected to affect the operations of organ procurement organizations or histocompatibility laboratories.

²⁶ See Minority Affairs Committee meeting summary, October 16, 2024. Available at https://optn.transplant.hrsa.gov/media/m3tkdxm0/20241016_mac_summary.pdf.

²⁷ “Modify Waiting Time for Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations”, OPTN, Policy Notice, accessed November 17, 2024, https://optn.transplant.hrsa.gov/media/njsllhg4/policy-notice_egfrwtmods_mac_ki.pdf.

²⁸ See Minority Affairs Committee meeting summary, November 18, 2024. Available at https://optn.transplant.hrsa.gov/media/44bmvorc/20241118_mac_summary.pdf.

²⁹ 42 CFR § 121.8(a)(7).

³⁰ 42 CFR § 121.10(b)(1)(iii).

Operations affecting Transplant Hospitals

This proposal would require every transplant program to document, in writing, the program's protocol for meeting the requirements of 3.7.D: *Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*, and to document the program's compliance with that protocol. Specifically, the MAC proposes three areas for which programs must have specific, written protocols and evidence of documentation in candidate medical records:

- Confirming candidate race
- Fulfilling notification requirements
- Seeking supporting documentation, including at a minimum what sources will be reviewed

Additionally, this proposal would require programs to ensure that all kidney candidates registered to the OPTN Waiting List on or after January 4, 2024 (the date after the program's attestations of compliance were due) are notified not only of the requirements of the programs within Policy 3.7.D, but also of candidate's eligibility and any outcomes of submitted wait 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.

Operations affecting the OPTN

The OPTN will plan for member communications to make them aware of this policy change and provide educational materials to aid transplant programs in meeting updated requirements. The OPTN will continue to review complete modification submission requests and process the approved waiting time modifications.

Potential Impact on Select Patient Populations

OPTN Policy 3.7.D, as effective on January 5, 2023, impacted eligible Black and African American kidney candidates by requiring an adjustment of their waiting time if they qualified per policy. The changes proposed here are not anticipated to have any additional impact on this or any other select patient population.

Projected Fiscal Impact

The Fiscal Impact Group (FIG), comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal.

Overall Projected Fiscal Impact

The proposal was determined to have a low overall fiscal impact on organ procurement organizations and transplant hospitals. No significant fiscal impacts were recorded for histocompatibility labs.

Projected Fiscal Impact on the OPTN

It is estimated that \$36,144 is needed for the development of this proposal. Development includes committee preparation and facilitation, proposal development, research and analysis, presentations, and compliance evaluation. It is estimated that \$21,785 would be needed to implement this proposal. Implementation would involve implementation communications and educational materials, updates to OPTN documents, templates, and processes. It is estimated that \$79,548 will be needed for ongoing support. Ongoing support will include member support, monitoring, compliance evaluation, and post-implementation analysis. The total for development, implementation, and ongoing support is estimated to be \$137,477.³¹

Projected Fiscal Impact on Organ Procurement Organizations

There is no expected fiscal impact on organ procurement organizations.

Projected Fiscal Impact on Transplant Hospitals

For transplant hospitals, the proposal is expected to have a low fiscal impact as additional education will be needed to notify staff of policy changes, but overall would not require new staffing. New protocols will need to be documented by staff.

Projected Fiscal Impact on Histocompatibility Laboratories

There is no expected fiscal impact on 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.”³² During site surveys of transplant hospitals, the OPTN Contractor will continue to review the hospital's internal policies and procedures for implementing the requirements of Policy 3.7.D, as well as verifying that those policies and procedures are documented in written protocol(s) that includes processes for meeting the requirements of Policy 3.7.D:

- Confirmation of candidate race
- Fulfilling notification requirements
- Seeking supporting documentation including what sources will be reviewed at a minimum.

The OPTN Contractor will also continue to review a sample of medical records, and any supporting documentation incorporated into the medical record, as evidence that the written protocol for OPTN Policy 3.7.D has been completed and the above requirements were fulfilled.

³¹ Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

³² 42 CFR §121.8(a)(7).

In addition, eGFR values entered into the OPTN Computer System will continue to be monitored. As is the case for all OPTN policy, all elements required by policy are subject to OPTN review, and members are required to provide documentation as requested.³³

Policy Evaluation

The MAC may issue ad hoc data requests as needed.

Conclusion

The Minority Affairs Committee seeks to update and enhance the requirements of transplant programs *in OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations* by proposing that every transplant program document, in writing, their protocols for implementing the requirements of the policy, specifically including processes for confirming candidate race, fulfilling notification requirements, and seeking supporting documentation, including, at a minimum, what sources will be reviewed. Additionally, the MAC aims to further enhance the policy by updating sections of *3.7.D.i Notification Requirement*, *3.7.D.ii Determination of Eligible Candidates*, and *3.7.D.iv Reporting Requirements for Kidney Transplant Programs*.

Considerations for the Community

The MAC is requesting public comment feedback, including input on the following questions:

- Are the more explicit notification requirements easy to understand or is additional clarification needed?
 - Should the policy specify that the search for candidates' supporting documentation must be completed prior to delivery of the eligibility notifications?
- Do community members support the application of updated, more explicit notification requirements for all candidates registered on or after January 4, 2024 (for candidates registered after the program's attestations of compliance were due)? Why or why not?
 - How much time would transplant programs need to complete notifications to candidates registered on or after January 4, 2024?
- What are other ways the OPTN can support patient and donor families by strengthening the evaluation requirements for eligibility for eGFR waiting time modifications?
- After reading the proposal and the updated policy language, do kidney transplant programs understand how to meet the policy requirements? Could any areas be further clarified?
- What additional education or guidance would be helpful to programs for implementation of this policy change?

³³ Member monitoring requirements are outlined in the OPTN Member Evaluation Plan and are effective upon policy implementation. OPTN Member Evaluation Plan, https://optn.transplant.hrsa.gov/media/5vebjkji/evaluation_plan.pdf.

Policy Language

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

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

2 Transplant hospitals must develop and comply with a written protocol that includes processes for
3 meeting the requirements of Policy 3.7.D, including:

- 4 • Confirming candidate race
5 • Fulfilling notification requirements
6 • Seeking supporting documentation including at a minimum, what sources will be reviewed

7 The transplant hospital must document that above processes were completed, including the results of
8 the review of sources, in the candidate's medical record.

9 **3.7.D.i Notification Requirement**

10 All designated kidney transplant programs must notify ~~every~~ candidates, including those registered
11 on or after 1/4/2024 that: at the transplant program of the responsibilities of the program pursuant
12 to Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR
13 Calculations.

- 14 1. Wait time modifications are available for candidates affected by race inclusive eGFR
15 calculations, as outlined in policy 3.7. D (education notification).
16 2. Of eligibility for a modification (eligibility notification).
17 3. All designated kidney transplant programs must notify all candidates of the eGFR modification
18 submission outcome, for applicable candidates (outcome notification).

19 **3.7.D.ii Determination of Eligible Candidates**

20 All designated kidney transplant programs must determine eligibility for a Waiting Time
21 Modification for Kidney Candidates affected by Race-Inclusive eGFR Calculations for each candidate
22 registered at the transplant program. A candidate is eligible for a waiting time modification if the
23 candidate is registered as Black or African American in the OPTN Computer System and has
24 documentation establishing that the candidate had an eGFR that was over 20 mL/min and would
25 have been 20 mL/min or less if a race-neutral calculation had been used. Every kidney transplant
26 candidate needs to be assessed for eligibility regardless of waiting time criteria or status, including
27 candidates registered for multi- organ transplant.

28 **3.7.D.iii Application for Waiting Time Modification**

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

- 32 1. Documentation of one of the following:
33 • The candidate's eGFR values for Black and non-Black candidates or

- 34 • The estimation of GFR with a race-inclusive calculation and a re-estimation of GFR with a
35 race-neutral calculation

- 36 2. The name and signature of the candidate’s physician or surgeon.

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

38 **3.7.D.iv Reporting Requirements for Kidney Transplant Programs**

39 All designated kidney transplant programs must submit an attestation to the OPTN by January 3,
40 2024, signed by the transplant program director (or their designee), affirming that the program has
41 completed both of the following:

- 42 • Notification to all candidates registered at the transplant program of their eligibility for a
43 waiting time modification according to this policy and
44 • Submission of eGFR waiting time modifications for all eligible candidates registered at the
45 transplant program.

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