

Briefing to the OPTN Board of Directors on

Monitor Ongoing eGFR Modification Policy Requirements

OPTN Minority Affairs Committee

*Prepared by: Kelley Poff
UNOS Policy Department*

Contents

Executive Summary	2
Purpose	3
Background	3
Proposal for Board Consideration	4
Overall Sentiment from Public Comment	12
Compliance Analysis	17
Implementation Considerations	19
Post-implementation Monitoring	20
Conclusion	21
Policy Language	22

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>
<i>Board of Directors Meeting:</i>	<i>June 9-10, 2025</i>

Executive Summary

The OPTN Minority Affairs Committee (MAC) submitted the *Monitor Ongoing eGFR Modification Policy Requirements* proposal to Winter 2025 OPTN Public Comment.¹ It proposed updates to ongoing policy requirements in *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*.

As of January 4, 2024, ongoing requirements for transplant programs include:²

- Continue to notify all newly registered kidney candidates of the requirements of the transplant program according to *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*.
- Continue to assess all newly registered kidney candidates to determine eligibility for a waiting time modification
- Submit completed waiting time modification requests to the OPTN

The MAC proposes the following updates to the ongoing requirements for Board consideration:

- Three areas for which programs must have specific, written protocols and thorough documentation to address the requirements of *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*³
 - Confirming candidate race
 - Fulfilling notification requirements
 - Seeking supporting documentation of eligibility, including, at a minimum, what sources will be reviewed
- Updates to the requirements of this policy to more explicitly include:⁴
 - *3.7.D.i. Notification Requirement*
 - Requirement for transplant programs to provide notifications to all kidney candidates of their eligibility for a waiting time modification based on race inclusive eGFR calculations

¹ *Monitor Ongoing eGFR Modification Policy Requirements*, OPTN Minority Affairs Committee, January 2025, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

² Waiting time modifications for candidates affected by race-inclusive eGFR calculations Toolkit, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

³ Meeting Summary for November 18, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

⁴ Ibid.

- 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*
 - Removal of outdated attestation language

Based on public comment feedback, the Committee made post public comment changes to include timeframes for compliance with the proposed policy requirements.⁵

- Transplant programs will have one year to comply with the proposed updated notification requirements for all candidates registered on or after January 4, 2024.⁶
- Transplant programs must notify candidates within 10 business days following the program's receipt of modification outcome from the OPTN. This outcome notification timeline requirement will be applied to candidates registered on or after this policy's implementation.⁷

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

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.⁸

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, 2024:⁹

- 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

⁵ *Monitor Ongoing eGFR Modification Policy Requirements Public Comment*, OPTN Minority Affairs Committee, January 2025. <https://optn.transplant.hrsa.gov> (accessed April 8, 2025).

⁶ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

⁷ Ibid.

⁸ *Establish OPTN Requirement for Race Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations*, OPTN Minority Affairs Committee, June 2022 <https://optn.transplant.hrsa.gov> (accessed November 17, 2024).

⁹ *Modify Waiting Time for Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations*, OPTN Minority Affairs Committee, December 2022, <https://optn.transplant.hrsa.gov> (accessed November 17, 2024).

- Submit attestation documentation to the OPTN of the program's compliance with the above requirements

As of January 4, 2024, ongoing requirements include:¹⁰

- 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 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 eGFR waiting time modifications.¹¹ To develop this proposal, the MAC collaborated with a variety of stakeholders, including members from the OPTN Kidney Transplantation Committee, OPTN Transplant Coordinators Committee (TCC), OPTN Transplant Administrators Committee (TAC), and MPSC.

Proposal for Board Consideration

The MAC proposes the following for Board consideration:

- Three areas for which programs must have specific, written protocols and thorough documentation to address the requirements of OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations¹²
 - Confirming candidate race
 - Fulfilling notification requirements
 - Seeking supporting documentation of eligibility, including, at a minimum, what sources will be reviewed
- Updates to the requirements of this policy to more explicitly include:¹³
 - *3.7.D.i. Notification Requirement*
 - Requirement for transplant programs to 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*
 - Removal of outdated attestation language

¹⁰ Waiting time modifications for candidates affected by race-inclusive eGFR calculations Toolkit, <https://optn.transplant.hrsa.gov> (accessed November 17, 2024).

¹¹ Meeting Summary for April 4, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

¹² Meeting Summary for November 18, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

¹³ Ibid.

Based on public comment feedback¹⁴, the Committee made post public comment changes to include timeframes for compliance with the proposed policy requirements.

- Transplant programs will have one year to comply with the proposed updated notification requirements for all candidates registered on or after January 4, 2024.¹⁵
- Transplant programs must notify candidates within 10 business days following the program's receipt of modification outcome from the OPTN. This outcome notification timeline requirement will be applied to candidates registered on or after this policy's implementation.¹⁶

Table 1 shows the proposed protocol and documentation requirements of *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations* based on registration timeframe.

Table 1: Protocol and documentation requirements based upon registration timeframe

Candidates registered between 1/4/24 and policy implementation date	Candidates registered on or after policy implementation date
Fulfilling updated notification requirements ¹⁷	Confirming candidate race
	Fulfilling updated notification requirements ¹⁸
	Outcome notification within 10 business days of receipt from OPTN
	Seeking supporting documentation of eligibility, including, at a minimum, what sources will be reviewed

Written Protocols

The following proposed requirements seek to provide more objective requirements for transplant programs related to *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*, as well as standardize the process for transplant programs to document implementation of the requirements.

Confirming candidate race

The MAC proposes that programs must document, in writing, protocols and maintain documentation for confirming each candidate's race upon registration.¹⁹ Candidate race is the first criterion that must be met when determining eligibility for an eGFR waiting time modification. Candidates that are registered on the OPTN Waiting List as Black or African American are eligible for a waiting time modification based on the use of race-inclusive eGFR, while candidates of other races are not. For example, a candidate who is registered on 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

¹⁴ Monitor Ongoing eGFR Modification Policy Requirements Public Comment, OPTN Minority Affairs Committee, January 2025, <https://optn.transplant.hrsa.gov> (accessed April 8, 2025).

¹⁵ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

¹⁶ Ibid.

¹⁷ Retrospective notification requirements include eligibility notifications for all candidates and outcome notifications for candidates with a submitted wait time modification.

¹⁸ Prospective notification requirements include education and eligibility notifications for all candidates, and outcome notifications for candidates with a submitted wait time modification. Transplant programs must notify candidates within 10 business days following the program's receipt of modification outcome from the OPTN.

¹⁹ Meeting Summary for July 15, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

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.²⁰

Public comment feedback on confirming candidate race

The Committee reviewed public comment feedback regarding the confirmation of candidate race and concluded that recommendations to require patient-validated data or additional verification measures did not align with the intent of the policy. The policy requires transplant programs to have protocols in place but does not speak to detailed or prescriptive requirements. The Committee concurred with comments emphasizing the importance of thoughtful implementation to avoid excluding candidates with multi-ethnic backgrounds and expressed support for the development of educational materials to guide programs. After considering this feedback, the Committee proceeded with no post public comment changes to this part of the proposal. The Committee reaffirmed its recommendation that transplant programs must establish written protocols and maintain documentation for confirming each candidate's race upon registration as proposed in public comment.²¹

Fulfilling notification requirements

The MAC proposed 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.²² 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. Feedback and discussion on proposed updates to *3.7.D.i Notification Requirement* can be found in the subsequent section of this paper.

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

The MAC proposed that programs document, in writing, their protocol for what sources will be reviewed in determining a candidate's eligibility for a waiting time modification, 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

²⁰ Meeting Summary for November 18, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²¹ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²² Meeting Summary for August 19, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

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 would be too prescriptive as sources vary between programs, depending upon size, availability of resources, and the EMR systems.²³ Members also agreed that programs listing their own sources would help the OPTN understand the types of resources to which each program has access.²⁴ The MAC proposed this as a prospective requirement that would be applied to candidates registered on or after the date this policy proposal is implemented.

Public comment feedback on fulfilling notification requirements and seeking supporting documentation

Overall, public comments reflected support for the intent and clarity of the proposed protocol and documentation standards related to fulfilling notification requirements and seeking supporting documentation.²⁵ Many stakeholders emphasized that these measures are critical for advancing equity, enhancing transparency, and promoting accountability across transplant programs. Commenters also valued the proposal's flexibility, which allows programs to tailor implementation and documentation approaches to align with their existing internal policies and workflows. After considering this feedback, the Committee proceeded with no post public comment changes to this part of the proposal.²⁶ The Committee reaffirmed its recommendations for adopting these protocol and documentation requirements as proposed in public comment.

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.

Updates to 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.²⁷ The MAC found this practice more

²³ Meeting Summary for September 30, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²⁴ Meeting Summary for July 15, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²⁵ *Monitor Ongoing eGFR Modification Policy Requirements Public Comment*, OPTN Minority Affairs Committee, January 2025, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²⁶ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²⁷ Meeting Summary for July 15, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

transparent, as it keeps candidates better informed on the status of their waiting time.²⁸ 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.²⁹

The MAC proposes that transplant programs provide the following information to 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

OPTN Policy 3.7.D.i: Notification Requirement currently mandates that kidney transplant programs notify all candidates that wait time modifications are available for those affected by race-inclusive eGFR calculations, as outlined in *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations*. The Committee proposes retaining this requirement in the ongoing policy and formally naming it the “education notification.” 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.³⁰ In most cases, there are opportunities to combine required information into either one or two communications to kidney candidates, thus reducing the administrative burden on transplant programs. 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.³¹ 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 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.³²

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

²⁸ Meeting Summary for July 15, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

²⁹ Meeting Summary for August 19, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

³⁰ Ibid.

³¹ Meeting Summary for July 15, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

³² Meeting Summary for August 19, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

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.³³ 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.³⁴

Public comment feedback on proposed changes 3.7.D.i. Notification Requirement

Overall, respondents expressed support for the proposed education, eligibility, and outcome notification requirements, provided they are applied prospectively to candidates registered on or after the policy's implementation date.³⁵ Commenters emphasized that patient notifications are a critical tool for ensuring transplant program accountability and empowering patients who wish to advocate for themselves.

As a post public- comment change, the MAC adopted a recommendation from the MPSC to establish a timeframe for notifying candidates following a program's receipt of the eGFR modification submission outcome from the OPTN.³⁶ Both committees agreed that such a requirement would enhance system transparency and enable more specific compliance monitoring. While the MPSC recommended a 30-day notification timeframe, the MAC determined that a 10-day notification timeframe would be more appropriate, aligning with existing OPTN policies such as *Policy 3.5: Patient Notification* and *Policy 3.6.C: Individual Waiting Time Transfers*. **Figure 1** illustrates an example of the proposed outcome notification process. The 10-day timeframe is calculated from the date the OPTN communicates the modification outcome to the transplant program. This requirement would be applied to candidates registered on or after the policy's implementation.

³³ Meeting Summary for November 18, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

³⁴ Ibid.

³⁵ Monitor Ongoing eGFR Modification Policy Requirements Public Comment, OPTN Minority Affairs Committee, January 2025, <https://optn.transplant.hrsa.gov> (accessed April 8, 2025).

³⁶ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

Figure 1. Outcome notification timeframe example



Public comment reflected a divided perspective within the transplant community regarding the proposed retrospective candidate notification requirements.³⁷ Several stakeholder organizations and individual commenters expressed opposition to the retroactive application, advocating instead for a prospective approach. These respondents emphasized that implementing retrospective notifications would place significant strain on program resources, disrupt day-to-day operations and competing priorities, and could result in duplicative efforts if candidates had already been notified. In contrast, those who supported the proposed retrospective requirement cited equity and transparency as foundational principles. Supportive commenters highlighted the importance of ensuring that all transplant candidates are informed of their eGFR modification status in a consistent and fair manner, regardless of when their registration occurred.

The MAC thoughtfully considered retention or removal of the proposed retrospective notification requirements. While the MAC acknowledged the additional workload the retrospective component of this policy may place on transplant programs, they concluded that ensuring kidney transplant candidates fully understand how *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations* impacts them outweighs the associated administrative burden. The MAC determined that retaining the retrospective notification requirement is the recommended course of action, as it prioritizes the patient and reinforces trust in the transplant process.³⁸

After determining they would recommend the retrospective notification requirement be retained as proposed in public comment, the MAC discussed an appropriate timeframe for its completion. Timeframes of six months, nine months, and one year were considered. The Committee emphasized that the timeframe should be uniform across all transplant programs, regardless of size, and should reflect the time needed for programs with the highest volume of affected candidates to comply. For these reasons, the MAC determined it would recommend that transplant programs be given one year from the policy's implementation date to complete the retrospective notification requirements.³⁹ To avoid additional policy language that is time bound, the MAC recommends this requirement be enacted

³⁷ Monitor Ongoing eGFR Modification Policy Requirements Public Comment, OPTN Minority Affairs Committee, January 2025, <https://optn.transplant.hrsa.gov> (accessed April 8, 2025).

³⁸ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

³⁹ Ibid.

through the Board’s approval and its effective date, rather than in the policy language itself. Compliance with the implementation of these notification requirements includes the one year time period to complete the retrospective notifications. If a transplant program has already notified a candidate registered on or after January 4, 2024, of their eGFR wait time eligibility and outcome, and can provide documentation of that notification to the OPTN, the program will not be required to notify the candidate again, as the policy requirements have been fulfilled.

The MAC determined that, to support timely compliance with the updated and ongoing requirements of OPTN Policy 3.7.D, they would adopt the MPSC’s recommendation for the OPTN to review each program’s written protocols within the first year of implementation. The MPSC recommended initiating these non-routine reviews shortly after implementation to ensure that compliance with the protocol requirement is evaluated across all programs within the first year.

3.7.D.ii Determination of Eligible Candidates

The MAC proposed the addition of 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.⁴⁰ This aims to explicitly require that every kidney candidate registered on 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.⁴¹ This attestation requirement served as demonstration of compliance from programs to the OPTN. The MAC recommends removing this language, as it is no longer applicable, and ongoing compliance will be monitored through other means.⁴²

Public comment feedback on proposed changes to 3.7.D.ii Determination of Eligible Candidates and 3.7.D.iv Reporting Requirements for Kidney Transplant Programs

There was no substantive feedback on proposed changes to OPTN Policies 3.7.D.ii: *Determination of Eligible Candidates* and 3.7.D.iv: *Reporting Requirements for Kidney Transplant Programs*. The Committee proceeded with no post public comment changes to this part of the proposal. The Committee reaffirmed its recommendations for adopting these protocol and documentation requirements as proposed in public comment.⁴³

⁴⁰Meeting Summary for October 16, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

⁴¹ *Modify Waiting Time for Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations*, OPTN Minority Affairs Committee, December 2022, <https://optn.transplant.hrsa.gov> (accessed November 17, 2024).

⁴² Meeting Summary for November 18, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

⁴³ Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

Overall Sentiment from Public Comment

The Committee welcomed all input on Monitor Ongoing eGFR Modification Policy Requirements, but asked for the following specific feedback during public comment:

- 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?

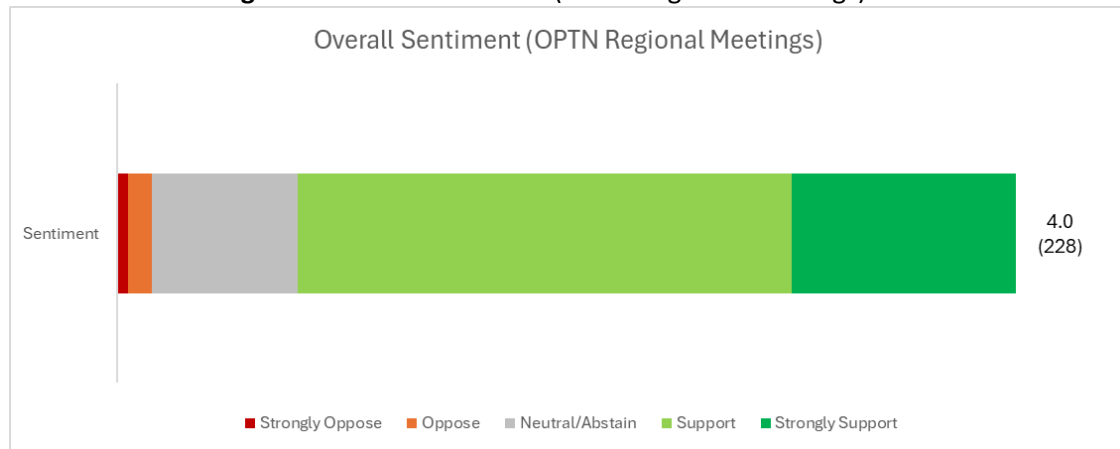
The proposal was released for public comment from January 21, 2025 - March 19, 2025. Respondents were able to provide sentiment and comments through regional meetings, committee meetings and a form on the OPTN website. Demographic information was collected from all respondents. It is important to consider the demographics participating in the public comment relevant to this proposal thereby ensuring the ultimate recommendation to the Board represents all stakeholders, even those whose volume of participation may be lower. The substance of each comment should be considered, with the volume of comments as a factor but not dispositive of the opinions represented.

Sentiment in Public Comment⁴⁴

Sentiment by Region (OPTN Regional Meetings)

Figure 2 shows the overall sentiment captured during OPTN regional meetings, based on a total of 228 responses. Overall, feedback has been generally supportive of the proposal, reflected in an average sentiment score of 4.0. However, several regions expressed specific concerns, which are discussed in greater detail in this analysis.

Figure 2. Overall Sentiment (OPTN Regional Meetings)^{45, 46}



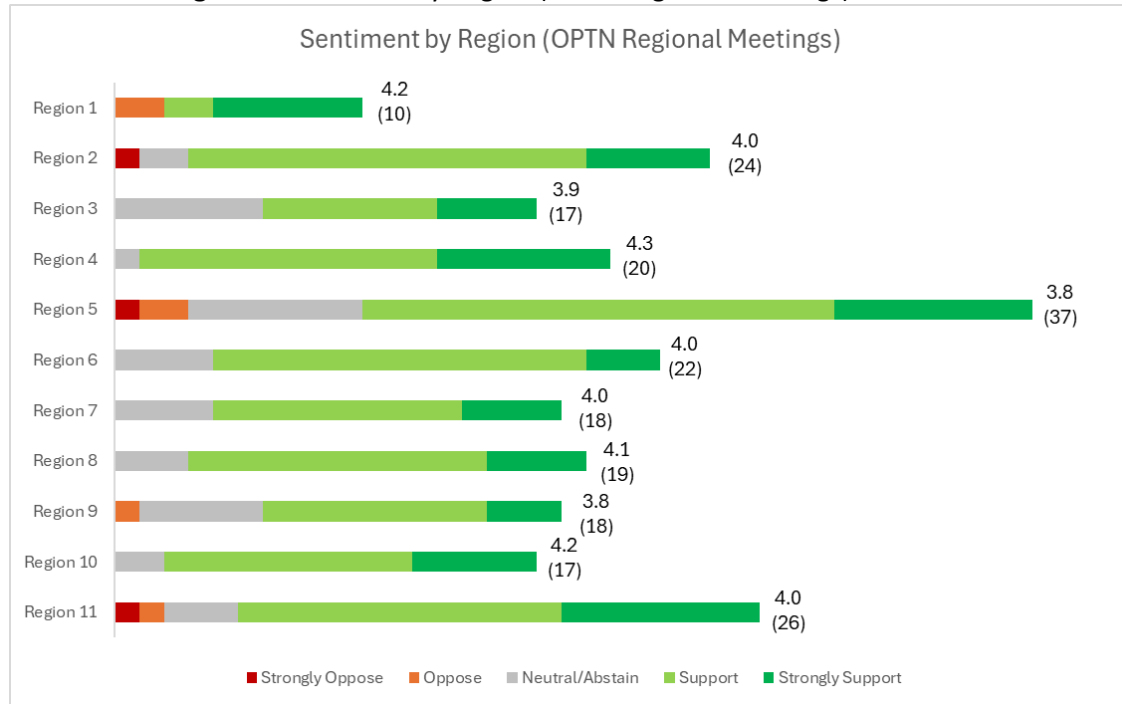
⁴⁴ Monitor Ongoing eGFR Modification Policy Requirements Public Comment, OPTN Minority Affairs Committee, January 2025, <https://optn.transplant.hrsa.gov> (accessed April 8, 2025).

⁴⁵ Sentiment is collected on public comment proposals during OPTN regional meetings and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5)

⁴⁶ The top number represents the average sentiment score, and the second number in parentheses represents the total number of respondents.

Figure 3 shows sentiment received at OPTN regional meetings by region. Sentiment by region was generally supportive. A few respondents in regions 1, 2, 5, 9, and 11 submitted opposing and/or strongly opposing sentiment.

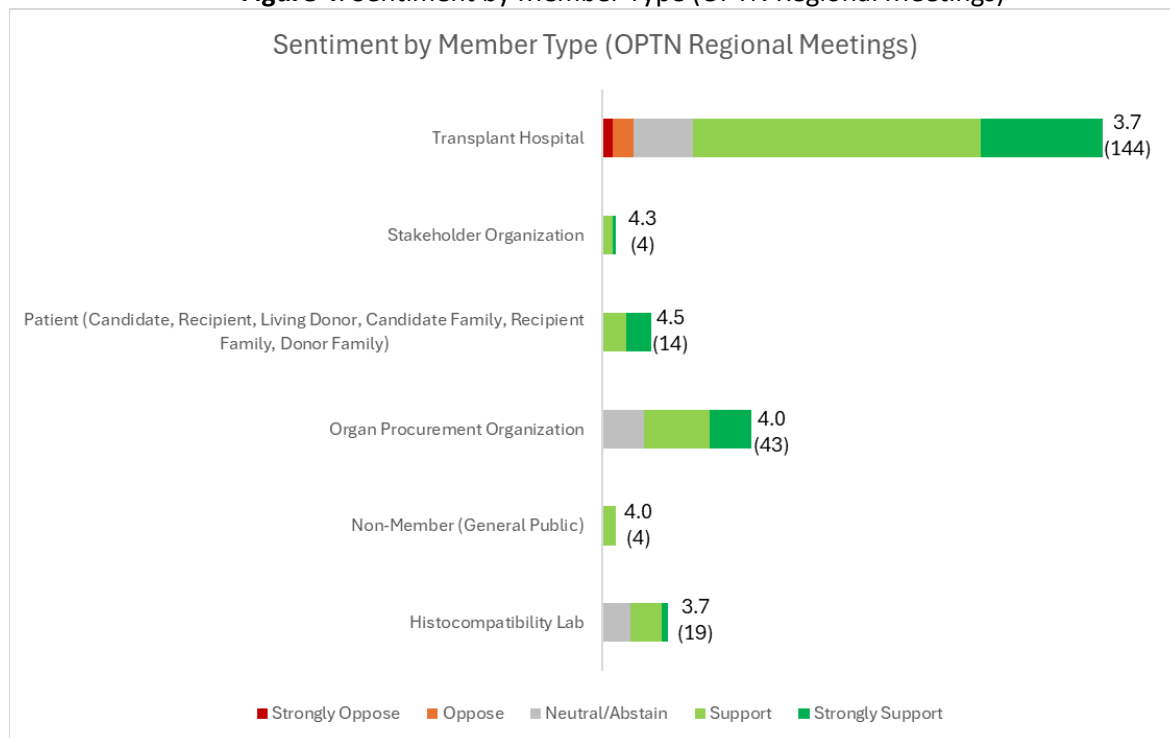
Figure 3. Sentiment by Region (OPTN Regional Meetings)⁴⁷



⁴⁷ The top number represents the average sentiment score, and the second number in parentheses represents the total number of respondents. The size of the bar reflects the total number of respondents per region.

Figure 4 shows sentiment received at OPTN regional meetings by member type. Sentiment by member type was generally supportive. Transplant hospitals submitted the most responses and were the only member type that expressed opposing or strongly opposing sentiment. All other member types submitted supportive, strongly supportive, and/or neutral sentiment.

Figure 4. Sentiment by Member Type (OPTN Regional Meetings)⁴⁸



Support on OPTN Website

The public comments submitted on the OPTN website were categorized based on the sentiment expressed in the text submitted. Each comment was analyzed to identify whether it conveyed support, opposition, or neutrality towards the proposal. The following definitions were used to ensure clarity and consistency in the categorization process:

- **Support:** The text of the public comment expressed a positive stance towards the proposal. Supportive comments typically contained language that endorsed, agreed with, or advocated for the proposal.
- **Do Not Support:** The text of the public comment expressed a negative stance towards the proposal. Comments that do not support the proposal contained language that opposed or disagreed with the proposal.
- **Neutral:** The text of the public comment did not clearly express a positive or negative stance towards the proposal. Neutral comments lacked definitive "support" or "not support" language or presented balanced viewpoints on the proposal.

Figure 5 shows the overall support from the OPTN website comments. Overall, 63% (15) of comments were supportive, 21% (5) of comments were neutral, and 17% (4) of comments did not support the proposal.

Figure 5. Overall Support (OPTN Website Comments)

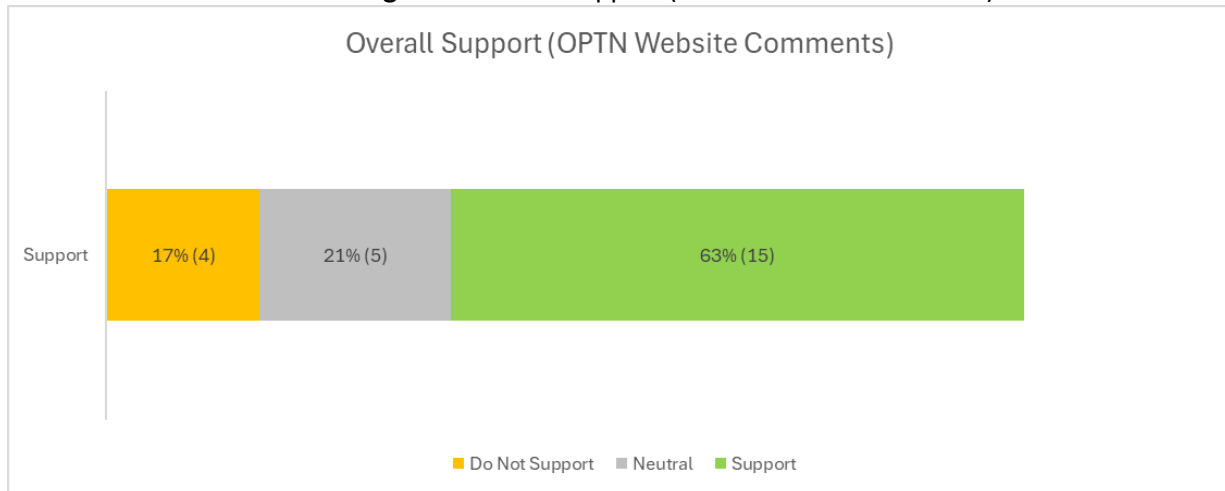
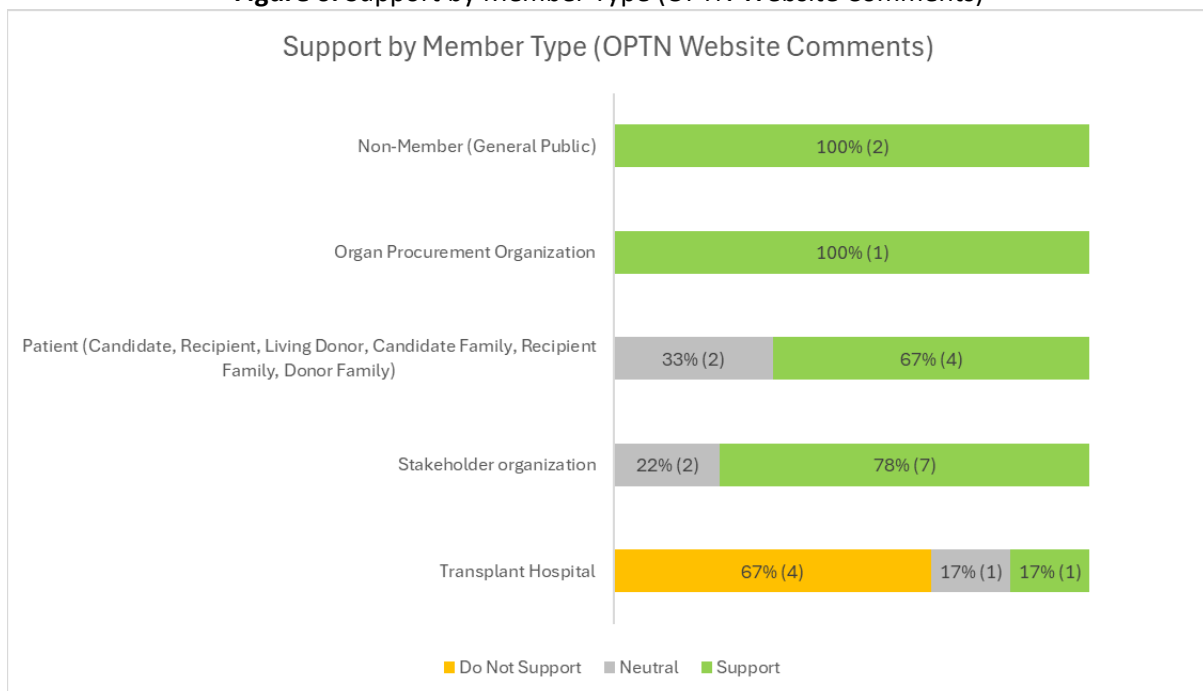


Figure 6 shows the support by member type on the OPTN website comments. Support by member type was generally supportive. Transplant hospitals were the only member type submitted comments that do not support the proposal. All other member types submitted supportive and/or neutral sentiment.

Figure 6. Support by Member Type (OPTN Website Comments)



⁴⁸ The top number represents the average sentiment score, and the second number in parentheses represents the total number of respondents. The size of the bar reflects the total number of respondents member type.

OPTN Committee Comments

The MAC received comments from the following OPTN Committees:

- OPTN Patient Affairs Committee
- OPTN Transplant Administrators Committee
- OPTN Transplant Coordinators Committee
- OPTN Membership and Professional Standards Committee
- OPTN Kidney Transplantation Committee

Stakeholder committees generally expressed support for the overall intent of the proposal, particularly its emphasis on enhancing transparency and communication with patients. OPTN Committees also found most of the proposed protocol and documentation requirements to be clearly articulated and appropriate for implementation.

All OPTN committees that provided feedback on the proposal, except for the Patient Affairs Committee, raised concerns or expressed opposition to the proposed retroactive notification requirements for candidates listed on or after January 4, 2024. Committees emphasized that implementing these requirements retrospectively would impose a significant strain on program resources, potentially impacting other critical operational functions.

The OPTN Committees also emphasized the need for clear, accessible educational materials for staff and patients. Transplant professionals who serve as committee members requested more information on documentation expectations. The OPTN Patient Affairs Committee recommended prioritizing outreach efforts to Black patients and providing clear instructions on how they can assist their transplant programs in determining eligibility for an eGFR modification.

Compliance Analysis

NOTA and OPTN Final Rule

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,”⁴⁹ and the OPTN Final Rule, which states the OPTN “shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”⁵⁰ This proposal addresses equitable allocation by standardizing the practices of how transplant programs are implementing the requirements of OPTN Policy 3.7.D, which created a wait time modification process for candidates impacted by the use of a Black race variable in the calculation of their eGFR.

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

⁴⁹ 42 U.S.C. 274(b)(2)(B).

⁵⁰ 42 C.F.R. § 121.4(a)(1).

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.”⁵¹
This proposal:

- **Is based on sound medical judgment.**⁵² The data and literature show that Black kidney candidate registrations were awarded a median of 1.7 years of waiting time between January 5, 2023 and January 3, 2024, when transplant programs submitted eGFR waiting time modifications as required by *OPTN Policy: 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations*. The proposed solution aims to better ensure that all kidney transplant programs are properly evaluating all candidates for eGFR waiting time modifications.
- **Is designed to...promote patient access to transplantation**⁵³ by giving similarly situated candidates equitable opportunities to receive an organ offer. Requiring transplant programs to follow updated policies and develop and follow procedures will ensure that transplant programs apply for a wait time modification for any eligible candidate.
- This proposal is not based on the candidate’s place of residence or place of listing⁵⁴

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

- Is designed to avoid futile transplants ⁵⁵
- Is designed to avoid wasting organs ⁵⁶

Transition Plan

The Final Rule requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.⁵⁷ The MAC proposes requiring transplant programs to retrospectively notify all kidney candidates registered on or after January 4, 2024, of their eligibility and any outcomes related to eGFR wait time modifications, and to document this in accordance with updated policy language and written protocols.⁵⁸ While current policy mandates assessing all candidates for modification eligibility, some programs may inconsistently notify candidates of their eligibility or outcome. MAC members, including patient representatives, emphasized the importance of consistent and transparent communication. January 4, 2024 was selected to align with prior attestations and ensure all candidates receive the same information, regardless of registration date.

OPTN Strategic Plan

Aligns with other important initiative: This project aligns with other important initiatives and intends to improve equity in access to transplants by addressing equity for Black kidney transplant candidates. This

⁵¹ 42 CFR §121.8(a).

⁵² 42 CFR §121.8(a)(1).

⁵³ 42 CFR §121.8(a)(5).

⁵⁴ 42 CFR §121.8(a)(8).

⁵⁵ 42 CFR §121.8(a)(5).

⁵⁶ Ibid.

⁵⁷ 42 C.F.R. § 121.8(d)(1).

⁵⁸ Meeting Summary for November 18, 2024, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 6, 2025).

project proposes that every kidney transplant program must maintain a written protocol that outlines the process for completing eGFR calculations and checking if new candidates on the OPTN Waiting List qualify for waiting time modifications. This aims to ensure that each potentially eligible candidate is being reviewed in accordance with the ongoing requirements of OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations, and eligible candidates are receiving eGFR waiting time modifications.

Implementation Considerations

The OPTN and transplant hospitals that perform kidney/kidney-pancreas, and multi-organ transplants that include kidney would need to take action to implement this proposal. This proposal is not anticipated to affect the operations of organ procurement organizations or histocompatibility laboratories.

Transplant Programs

Operational Considerations

This proposal would require every transplant program to document, in writing, the program's protocol for meeting the requirements of *Policy 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 on 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 *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*, but also of candidate's eligibility and any outcomes of submitted wait time modifications. Programs are expected to complete this retrospective review and notification within one year of implementation. Programs would be required to notify candidates within 10 business days of receiving the modification outcome from the OPTN. This notification timeline would apply to candidates registered on or after the policy's implementation date.

Fiscal Impact

This proposal is expected to have a medium-high fiscal impact on transplant hospitals as retrospective and continued notifications accrue. 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.

Histocompatibility Laboratories

Operational Considerations

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Fiscal Impact

There is no expected fiscal impact on histocompatibility laboratories.

Organ Procurement Organizations

Operational Considerations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Fiscal Impact

There is no expected fiscal impact on organ procurement organizations.

OPTN

Operational Considerations

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. The OPTN will conduct site surveys of transplant hospitals which will include the requirements in this proposal.

Resource Estimates

It is estimated that \$20,300 will be needed to implement this proposal. Implementation will include reviewing and preparing implementation communications and educational materials and community outreach. It is estimated that \$103,893 will be needed for ongoing support. Ongoing support will consist of member support and education, site surveys of transplant hospitals, and overall compliance monitoring. The total estimate including implementation and ongoing support is \$124,192.⁵⁹

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

⁵⁹ "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."

program.”⁶⁰ Implementation of the requirements in *OPTN Policy 3.7.D* includes the retrospective notification requirements for those candidates registered on or after 1/4/2024 until the implementation date of this proposal. Members will have one year from the date of implementation to complete the retrospective notification requirements for adult candidates registered for a kidney, kidney-pancreas, or multi-organ combination that includes a kidney. Additionally, within the first year of implementation, the OPTN Contractor will inquire with all transplant hospitals to review and verify that all written protocol(s) meet the requirements of *OPTN Policy 3.7.D*.

During routine monitoring, the OPTN Contractor will review transplant hospital written protocols to verify that they include processes for meeting the requirements of *OPTN 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 review a sample of medical records, and any supporting documentation incorporated into the medical record, as evidence that the written protocols for *OPTN Policy 3.7.D* have been completed and the above requirements were fulfilled.

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.⁶¹

Policy Evaluation

Compliance with this policy will be evaluated and aggregate results shared with the Committee at approximately 1 year, 2 years, and 3 years post- implementation.

Conclusion

This proposal, sponsored by the MAC 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*.

As a result of post–public comment discussions, the Committee recommended retaining the retrospective notification requirement and establishing a one year timeframe for transplant programs to comply.⁶² Additionally, the Committee recommends requiring programs to provide outcome notifications to kidney candidates who had an eGFR wait time modification submitted on their behalf within 10 business days of receiving the modification outcome from the OPTN.⁶³

⁶⁰ 42 CFR §121.8(a)(7).

⁶¹ 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/5vebikii/evaluation_plan.pdf.

⁶² Meeting Summary for March 31, 2025, OPTN Minority Affairs Committee, <https://optn.transplant.hrsa.gov> (accessed May 15, 2025).

⁶³ Ibid.

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.

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

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

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

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

3.7.D.i Notification Requirement

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

1. Programs are required to submit eGFR waiting time modifications for candidates affected by race inclusive eGFR calculations ~~Wait time modifications are available for candidates affected by race inclusive eGFR calculations, as outlined in policy 3.7. D (education notification).~~
2. ~~Of Whether or not the candidates is~~ are eligible eligibility for an eGFR modification (eligibility notification).
3. ~~All designated kidney transplant programs must notify all candidates of~~ The outcome of the eGFR modification submission the eGFR modification submission outcome, for applicable candidates (outcome notification).
 - Programs must notify candidates within 10 business days following the program's receipt of modification outcome from the OPTN.

3.7.D.ii Determination of Eligible Candidates

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

3.7.D.iii Application for Waiting Time Modification

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

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

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

3.7.D.iv Reporting Requirements for Kidney Transplant Programs

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

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

#