OPTN

Public Comment Proposal

Require Patient Notification for Waitlist Status Changes

OPTN Transplant Coordinators Committee

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Contents

Executive Summary	2
Purpose	3
Inactive Candidates on the Waiting List	3
Overview of Proposal	8
NOTA and Final Rule Analysis	8
Implementation Considerations	9

Require Patient Notification for Waitlist Status Changes

Affected Policy: *3.5: Patient Notification*
Sponsoring Committee: *Transplant Coordinators Committee*
Public Comment Period: *August 27, 2025 - October 1, 2025*

Executive Summary

Currently, *OPTN Policy 3.5: Patient Notification* includes notification requirements for when:

- A patient is registered on the waiting list
- A patient's evaluation for transplant is complete and the patient is not registered on the waiting list at that time
- A patient is removed from the waiting list for reasons other than transplant or death

The Transplant Coordinators Committee (TCC) proposes an update to *OPTN Policy 3.5: Patient Notification* to add a requirement for notification related to patient activation and inactivation. Transplant programs would be responsible for communicating to candidates whenever their waitlist status has changed. The project aims to alert patients who are moved to active from inactive status, or inactive from active status, adding transparency and empowering patients to work with their transplant team to ensure their listing status is accurate.[1] The TCC is asking the community whether the proposed notification should be required in writing, or whether alternative forms of communication with candidates (by phone or in a conversation) would be acceptable if still documented in the candidate's record.

[1] Meeting Summary for March 10, 2025, OPTN Transplant Coordinators Committee, https://optn.transplant.hrsa.gov/media/ulinhczh/20250310_tcc-meeting-summary.pdf (accessed May 15, 2025).

Purpose

The TCC proposes *OPTN Policy 3.5: Patient Notification* be updated to include a requirement that transplant programs must notify candidates within 10 days of a waiting list status change. Notifying candidates within 10 days promotes transparency and empowers patients to work with their transplant team to ensure their listing status is accurate. Ensuring that candidates who are healthy enough for transplant are active on the waiting list is critical for these candidates to receive offers for life saving organs. It is also critical that centers maintain an accurate list of those candidates listed as inactive and share that information with the impacted patients. This proposal would not only inform the candidate when they are listed as inactive, and thus ineligible to receive organs offers, but would also allow the candidate an opportunity to resolve the cause for their inactive status.

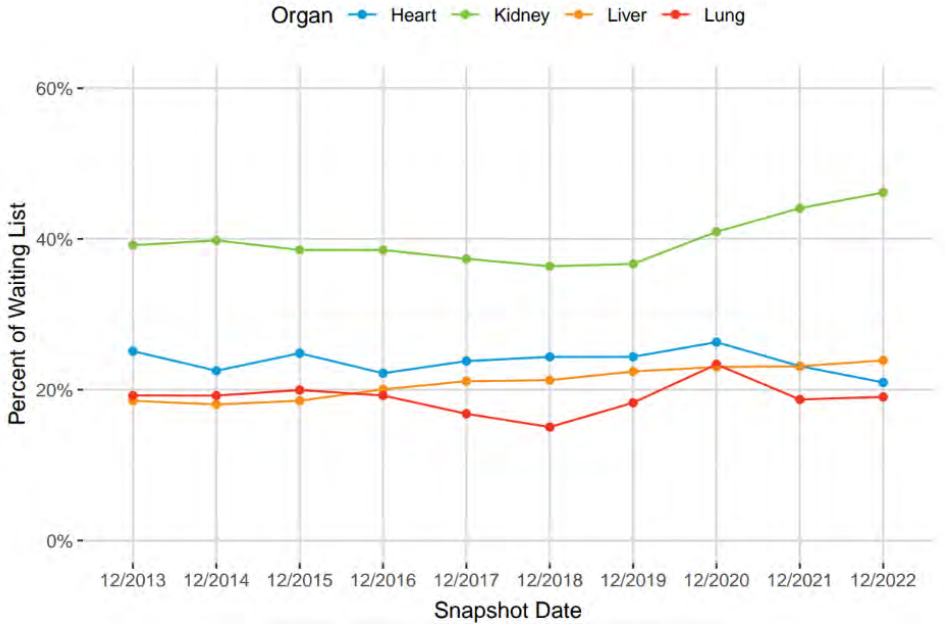
Inactive Candidates on the Waiting List

As defined in OPTN Policy, an inactive candidate is "A candidate that is temporarily unavailable or unsuitable for transplantation and appears as inactive on the waiting list."[2] Candidates assigned to an inactive status while on the waiting list are ineligible from receiving organ offers during allocation but may still accrue waiting time (only for lung, kidney, and pancreas candidates). While transplant programs may communicate status changes from inactive to active or from active to inactive, OPTN policy has not required this communication, and patients may not receive status changes if their program processes do not include notification of status change.

Reasons for candidates to be listed as inactive varies by organ, as does the proportion of inactive to active candidates. **Figure 1** shows that the proportion of inactive kidney candidates ranged from 40 to 46% of the overall kidney waiting list from December 2013 to December 2022, while 20 to 25% of heart, liver, and lung waiting lists were comprised of inactive candidates during the same time range.[3]

[2] OPTN Policy 1.2: *Definitions*. (May 16, 2025).
[3] OPTN Data Request. "Inactive Registrations by Organ." Prepared for Patient Affairs Committee Conference Call, March 03, 2023.

Figure 1: Percentage of Inactive Registrations at Each Waiting List Snapshot Date by Organ



A single day snapshot (December 31, 2022) shows the variation in inactive status by organ type:

- 49.73% of inactive kidney candidates were designated as inactive due to incomplete workup, and 23.93% because they were temporarily too sick (**Figure 2**).
- 22.75% of inactive liver candidates were inactive due to temporarily being too sick and 21.24% had incomplete workup (**Figure 3**).
- 29.56% of inactive heart candidates were temporarily too sick, while 22.91% were temporarily too well (**Figure 4**).

The most common reasons for inactivity across organ type (**Figures 2**, **3**, and **4** below) included incomplete workup, candidate's health, insurance issues or candidate choice.

The impact of inactive status may vary by organ type, as inactive lung, kidney, and pancreas candidates continue to accrue wait time while inactive heart and liver candidates do not. Inactivity on the waitlist has been linked to higher mortality rates for kidney transplant candidates; however, according to a 2019 study, "the implications and impact of a wait-list inactive status change on a patients' future chances of obtaining a kidney transplant remain unknown."[4] Inactive candidates may or may not be aware of their status, its reasoning, or its impact, highlighting the need for a required status change notification.

[4] S. Kulkarni et al. "Association of Racial Disparities With Access to Kidney Transplant After the Implementation of the New Kidney Allocation System." *JAMA Surgery* 154, no. 7 (2019) 618–625. https://doi.org/10.1001/jamasurg.2019.0512.

Figure 2: Number and Percentage of Inactive Kidney Registrations Using Each Inactive Code on 12/31/2022

Inactive Reason	Count (%)
Candidate work-up incomplete	22292 (49.73%)
Temporarily too sick	10729 (23.93%)
Temporarily too well	3709 (8.27%)
Insurance issues	2782 (6.21%)
Candidate choice	1737 (3.87%)
Weight currently inappropriate for transplant	1337 (2.98%)
COVID-19 Precaution	765 (1.71%)
Medical non-compliance	535 (1.19%)
Candidate for living donor transplant only	388 (0.87%)
Candidate cannot be contacted	220 (0.49%)
Inappropriate substance use	154 (0.34%)
TX Pending	133 (0.30%)
Not Reported	38 (0.08%)
Physician/Surgeon unavailable	5 (0.01%)
TX'ed - removal pending UNET data correction	2 (0.00%)
Total	44826 (100.00%)

Figure 3: Number and Percentage of Inactive Liver Registrations Using Each Inactive Code on 12/31/2022

Inactive Reason	Count (%)
Temporarily too sick	600 (22.75%)
Candidate work-up incomplete	560 (21.24%)
Temporarily too well	481 (18.24%)
Candidate choice	352 (13.35%)
Insurance issues	218 (8.27%)
Inappropriate substance use	171 (6.48%)
COVID-19 Precaution	97 (3.68%)
Medical non-compliance	83 (3.15%)
Candidate cannot be contacted	37 (1.40%)
Weight currently inappropriate for transplant	29 (1.10%)
Candidate for living donor transplant only	7 (0.27%)
Physician/Surgeon unavailable	2 (0.08%)
Total	2637 (100.00%)

Figure 4: Number and Percentage of Inactive Heart Registrations Using Each Inactive Code on 12/31/2022

Inactive Reason	Count (%)
Temporarily too sick	209 (29.56%)
Temporarily too well	162 (22.91%)
Candidate choice	74 (10.47%)
Inactivation due to VAD implantation and/or VAD complication	55 (7.78%)
COVID-19 Precaution	42 (5.94%)
Insurance issues	41 (5.80%)
Weight currently inappropriate for transplant	41 (5.80%)
Medical non-compliance	25 (3.54%)
Inappropriate substance use	20 (2.83%)
Not Reported	13 (1.84%)
Candidate work-up incomplete	10 (1.41%)
Physician/Surgeon unavailable	9 (1.27%)
Candidate cannot be contacted	6 (0.85%)
Total	707 (100.00%)

Figure 5 captures how often a candidate's status changes from inactive to active or active to inactive, stratified by organ type. It shows that the number of status changes on average is increasing for lung candidates, while remaining more consistent for kidney candidates over time. Figure 5 demonstrates the potential challenges for transplant programs in communicating status changes with candidates: if a program has 10 liver candidates who each have 15 status changes (the average number for liver candidates in 2022), there would be 150 notifications. This scenario highlights the question the TCC is asking the community regarding whether notifications need to be written or whether they could be a conversation that is later documented; the latter option would be less burdensome to programs but still inform patients when statuses change.

Figure 5: Average Status Changes per Year Waiting by Organ 2013-2022

Year	Heart	Kidney	Liver	Lung
2013	12.13	10.44	11.48	10.02
2014	11.53	11.54	11.89	10.64
2015	12.25	10.63	11.98	11.52
2016	11.37	10.72	11.66	10.41
2017	13.68	10.60	11.83	11.37
2018	13.86	10.44	12.15	11.57
2019	14.87	10.75	13.39	12.34
2020	17.11	11.45	13.54	14.05
2021	15.32	11.78	14.64	18.68
2022	16.45	12.43	14.90	17.66

Background and Development of Current Project

In 2014, the TCC proposed requiring status notification be sent to inactive candidates after 90 and 365 consecutive days and then annually thereafter for as long as the candidate remains inactive.[5] The TCC reviewed public comment feedback, and found that a majority responses from regional meetings, OPTN Committees, and individual public feedback were not supportive and emphasized concern around potential burden of implementation within programs and questions about the ability of programs to comply with the proposed changes.[6] The TCC discussed the future of the proposal and voted not to submit it to the Board or develop a guidance document at that time due to community concern about the administrative burden associated with requiring several subsequent notifications.[7]

In the beginning of 2023, the Patient Affairs Committee (PAC) expressed concern about the volume of candidates inactive on the waitlist, and whether those candidates know they are inactive.[8] The PAC sought further information around patient waitlist status notification in 2023 and presented their findings to TCC at their January 2024 meeting where TCC members discussed current transplant practices.[9] Members discussed their current transplant program practices and how they align with Center for Medicare and Medicaid Services regulations. This discussion led to the current project, in which policy has been identified by OPTN Board leadership as a step towards greater patient awareness and empowerment.[10]

In February 2025, the TCC was directed by the Executive Committee to take on a project addressing waiting list inactive notifications. The Committee proposes modifying *OPTN Policy 3.5: Patient Notification* to require patient notification when patients are moved to inactive status, or to active status, adding transparency and empowering patients to work with their transplant team to ensure their listing status is accurate.[11]

The TCC is asking the community for feedback regarding whether notification needs to be in a written format or whether it can be communicated through phone or conversation and documented in the candidate's record.[12] This reflects feedback from the Transplant Administrators Committee (TAC), which noted that if candidates have several status changes within a short timeframe, it may cause an influx of notifications.[13] This concern is also reflected in the data on status change frequency included in **Figure**

[5] *Proposal to Notify Patients Having an Extended Inactive Status*, OPTN Transplant Coordinators Committee, March 2014, https://optn.transplant.hrsa.gov/media/1443/pubcommentpropsub_344.pdf (accessed May 9, 2025).
[6] *Report to the Board of Directors*, OPTN Transplant Coordinators Committee, November 2014, https://optn.transplant.hrsa.gov/media/1330/tcc_boardreport_20140702.pdf (accessed May 15, 2025).
[7] Ibid.
[8] Meeting Summary for March 21, 2023, OPTN Patient Affairs Committee, https://optn.transplant.hrsa.gov/media/jp3jzcxj/20230321_optn_pac_meeting_summary.pdf (accessed May 15, 2025).
[9] Meeting Summary for January 31, 2024, OPTN Transplant Coordinators Committee, https://optn.transplant.hrsa.gov/media/lxunhekx/01312024_optn_transplant-coordinators-committe-meeting-summary.pdf (accessed May 15, 2025).
[10] Meeting Summary for March 6, 2025, OPTN Executive Committee, https://optn.transplant.hrsa.gov/media/knylqahg/optn-execcommtngsmmry-030625-508.pdf (accessed June 25, 2025).
[11] Meeting Summary for March 10, 2025, OPTN Transplant Coordinators Committee, https://optn.transplant.hrsa.gov/media/ulinhczh/20250310_tcc-meeting-summary.pdf (accessed May 15, 2025).
[12] 42 C.F.R. §482.94(c)(2) does not specify that the notification must be written but does require documentation.
[13] Meeting Summary for June 23, 2025 OPTN Transplant Administrators Committee, https://optn.transplant.hrsa.gov/media/egfjv1fn/20250623_tac-meeting-summary.pdf (accessed July 1, 2025).

5[14]. The current proposal requires written notification, which is consistent with other notification requirements, but the TCC is seeking feedback from the community about the appropriate form of notification. It is also continuing to review data regarding the frequency of candidate status changes across organ type to ensure that the solution reflects the appropriate level of flexibility for programs to comply with the policy.

Overview of Proposal

The TCC proposes updating *Table 3-2: Transplant Hospital Patient Notification Requirements* in *OPTN Policy 3.5: Patient Notification* to require patient notification when patients are moved to inactive status or to active status from inactive. The proposed language would require that when a candidate has a status change from active to inactive or from inactive to active, the transplant hospital must send a written notification of the change within 10 business days to the candidate. The TCC is considering public comment feedback, as well as a review of relevant data, to evaluate the necessity of the notification being written; if public comment reflects community concerns with the burden of that solution, the TCC may provide a modified proposal to the Board to allow conversations with candidates in lieu of written notification, as long as the conversations are documented in the candidate's medical record.

NOTA and Final Rule Analysis

The Committee submits this project for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "establish… a national list of individuals who need organs."[15] The OPTN Final Rule permits transplant hospitals to list individuals for transplant, "consistent with the OPTN's criteria under §121.8(b)(1)," which includes criteria for addition and removal of candidates from organ transplant waiting lists.[16] Individuals in need of an organ transplant are registered on the OPTN Waiting List in the OPTN Computer System, where instead of completely removing a candidate from the waiting list, transplant programs may change a candidate's status to "inactive" if the candidate is temporarily unable to receive organ offers, for example, due to an infection or due to an incomplete work-up (e.g. the candidate needs to complete additional testing). The TCC proposes requiring transplant programs to notify candidates if they are placed in inactive status or changed from inactive to active so that candidates are aware when they will not receive organ offers. Additionally, candidates can take any actions required of them to return to active status as soon as possible to resume receiving organ offers.

[14] OPTN Data Request. "Inactive Registrations by Organ." Prepared for Patient Affairs Committee Conference Call, March 03, 2023.
[15] 42 U.S.C. §274(b)(2)(A)(i).
[16] 42 CFR §121.5(a); §121.8(b)(1).

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Transplant programs will need to notify candidates within 10 days of a waiting list status change. Programs without a status change notification system in place may need to update procedures. Program-wide notification of this change and training for staff may be needed.

Operations affecting Histocompatibility Laboratories

There is no expected impact to histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

There is no expected impact to organ procurement organizations.

Operations affecting the OPTN

Upon implementation, this proposal will require a new notification requirement that will be evaluated during transplant hospital site surveys according to the OPTN Evaluation Plan for *OPTN Policy 3.5*. Site survey staff will interview relevant staff to verify that hospital staff practices align with OPTN policy.

Transition Procedures

The Final Rule also requires the OPTN, when it "revises organ allocation policies under [42 C.F.R. §121.8],…[to] consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies."[17] The TCC determined that the notification requirement will apply to candidates who have status changes after implementation of the policy occurs. Notification of any waitlist status changes that occurred prior to the policy implementation would not be required.

Potential Impact on Select Patient Populations

This proposal may have a greater impact on Hispanic and Black kidney candidates who have historically been less likely to resolve issues related to inactive status than white candidates.[18] A 2019 examination of the racial disparities of inactive kidney candidates found that Hispanic and Black candidates had a disproportionate number of inactive candidates given their percentage of overall candidates on the waiting list. This same study also found that white candidates were more successful than Hispanic or Black candidates in moving from inactive to active status.[19] This proposal may address an inequity in the disproportionate number of Black and Hispanic kidney candidates who are inactive on the waiting list by requiring candidate awareness of their status changes, which may empower candidates to address the cause of the status change.

[17] 42 C.F.R. § 121.8(d)(1).

[18] S. Kulkarni et al. "Association of Racial Disparities With Access to Kidney Transplant After the Implementation of the New Kidney Allocation System." *JAMA Surgery* 154, no. 7 (2019) 618–625. https://doi.org/10.1001/jamasurg.2019.0512.

[19] Ibid.

Projected Fiscal Impact

The Fiscal Impact Advisory Group, comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rate projects 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

This proposal is expected to have a low impact on transplant programs. There were no significant fiscal impacts indicated with this proposal for histocompatibility laboratories and organ procurement organizations.

Project Fiscal Impact on Transplant Hospitals

There is a low expected fiscal impact on transplant programs as they adjust to policy. Programs that do not currently notify patient waitlist status changes may accrue further costs to develop notification procedure.

Projected Fiscal Impact on Organ Procurement Organizations

There were no significant fiscal impacts indicated with this proposal.

Projected Fiscal Impact on Histocompatibility Laboratories

There were no significant fiscal impacts indicated with this proposal.

Projected Fiscal Impact on the OPTN

It is estimated that $(redacted) would be needed to implement this proposal. Implementation would involve preparing implementation communications and educational materials, community outreach, and updates to the OPTN website. It is estimated that $(redacted) will be needed for ongoing support. Ongoing support includes member support, compliance monitoring, and monitoring reports at the 6-month, 1-year, and 2-year timeframes. The total estimate for implementation and ongoing support is $(redacted).[20]

Post-implementation Monitoring

Member Compliance

The Final Rule requires that 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."[21] During site surveys of transplant hospitals, an OPTN Contractor, on behalf of the OPTN, will continue to verify that

[20] 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. Resource estimates are exempted from public disclosure under the Freedom of Information Act exemption 4.

[21] 42 CFR §121.8(a)(7).

transplant hospital practices align with *OPTN Policy 3.5 Patient Notification* requirements. This will include the requirement that patients are notified of changes in their status within the requisite 10 business day period. All elements required by policy are subject to OPTN review, and members are required to provide documentation as requested.

Policy Evaluation

The Committee intends that through this policy change candidates will be more aware of their waitlist status. The Committee considers the amount of time candidates spend in inactive status as the key metric to assess the outcome of the proposed change.

Metrics to be evaluated include:

1. Time candidates spend in inactive status, by inactive reason and/or organ.
2. Total number of status changes (active to inactive or inactive to active) by organ.

These metrics will be reviewed at approximately six months, one year, and two years post-implementation and will be compared pre- to post-implementation.

Conclusion

The Committee proposes updating *OPTN Policy 3.5: Patient Notification* to include a requirement for a written notification of candidate inactivation or activation. Requiring this notification in policy supports transparency and patient awareness. Community feedback will inform the method of notification requirement and could inform future efforts related to patient engagement.

Considerations for the Community

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

- Do community members think that written notification is necessary, or would documentation of notifications, including conversations, be sufficient?
- Do patients & patient families and caregivers support notifying candidates when their waiting list status changes?
    - Is there additional information that would be helpful to include in the patient notification, other than waiting list status?
    - This proposal lays the groundwork for future efforts to improve patient awareness and engagement in their transplant journey. Are there additional tools or efforts, such as a patient portal, that you feel would be helpful to better inform and engage patients in the future?
- What education or guidance would be helpful for patients & patient families and caregivers?
- Do transplant programs feel that this notification change is feasible or have concern about the level of burden? If there is concern about burden, please specify.
- What education or guidance would be helpful for programs to support the implementation of this proposal?

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.

3.5 Patient Notification

Transplant hospitals must notify patients in writing according to *Table 3-2* below:

Table 3-2: Transplant Hospital Patient Notification Requirements

When:	The transplant hospital must send a notification within 10 business days with the following information:
The patient is registered on the waiting list	The date the patient was registered.
The patient's evaluation for transplant is complete and the patient is *not* registered on the waiting list	That the patient's evaluation has been completed and the patient will not be registered on the waiting list at this time.
The patient is removed from the waiting list for reasons *other than* transplant or death	That the patient has been removed from the waiting list.
The patient has a status change from active to inactive or inactive to active	That the patient status has changed from active to inactive or inactive to active

Each written patient notification required in *Table 3-2* must also include and refer to the *OPTN Contractor's Patient Information Letter*, which provides the number for the toll-free Patient Services Line. The transplant hospital must document these notifications.

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