

**OPTN Patient Affairs Committee**  
**Patient Awareness of Listing Status (PALS) Subcommittee**  
**Meeting Summary**  
**August 13, 2024**  
**Conference Call**

**Garrett W. Erdle, Subcommittee Chair**

**Introduction**

The Patient Affairs Committee’s Patient Awareness of Listing Status (PALS) Subcommittee met via Teams teleconference on August 13, 2024, to discuss the following agenda items:

1. Welcome and Announcements
2. Current Requirements Related to Candidate Notifications
3. Review of Subcommittee’s Potential Solution Framework
4. Next Steps: Policy Oversight Committee Project Review/Approval

The following is a summary of the Subcommittee’s discussion.

**1. Welcome and Announcements**

The Chair thanked participants for working on how to operationalize this effort. He believes that this will certainly resonate with the patient community and improve upon their experience.

**2. Current Requirements Related to Candidate Notification**

No decisions were made.

Summary of discussion:

A recap of relevant policy regarding patient notification for both OPTN and CMS was presented by OPTN Contractor staff. OPTN Policy 3.5 *Patient Notification* requires written patient notification at time of registration on the wait list, if evaluation is completed and a patient is not registered on the wait list, or if a patient is removed from the wait list for reasons other than death or transplant<sup>1</sup>. CMS regulations include similar language<sup>2</sup>. There is no specific written requirement regarding notification of inactive status in OPTN or CMS language. With the exception of heart and liver, for which candidates at inactive status do not accrue wait time, other organ candidates listed at an inactive status do accrue wait time. Intestine candidate waiting time is capped at 30 cumulative days while set to inactive status, while remaining organ candidates accrue unlimited wait time.

OPTN Contractor staff noted that the type of policy modification or addition needed for this project will be dependent on the solution desired. If the OPTN is communicating status information directly to patients, policy may not be required in OPTN Policy 3.5, which outlines notification requirements for

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<sup>1</sup> [https://optn.transplant.hrsa.gov/media/eavh5bf3/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf), Accessed 9/9/2024

<sup>2</sup> <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E/subject-group-ECFRc4be2badf376a95/section-482.94>. Accessed on 9/9/2024

OPTN members (e.g. transplant programs). However, if candidates had questions regarding their inactive status, or how to get back to active status, they would still need to contract their listing transplant program.

### 3. Review of Subcommittee's Potential Solution Framework

No decisions were made by the Subcommittee.
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#### Discussion Summary:

Since the July call, the Subcommittee had developed a proposed framework for communicating in simple terms whether a candidate is active or inactive on the wait list. The immediate-past Committee Chair had previously discussed this concept informally with leadership from the Minority Affairs, Ethics, Living Donor, and Transplant Coordinator Committees. He noted that all seemed receptive and generally supportive of this effort, noting that this type of access would not expose anything that a patient should not already be aware of. He highlighted benefits noted in the framework.

#### *Benefits to providing this information:*

- *Avoid a candidate not receiving an offer due to possibly being mislabeled as Inactive.*
- *Encourage patients to be engaged in their transplant care. If labeled incorrectly, patients could contact their coordinator to take corrective action to change the status.*
- *Empower patients to improve the potential of changing their waitlist status. If patients are correctly labeled Inactive, there may be steps they can take to change their status labeling (complete labs, improve the diet, weight loss, etc.) making the real-time understanding of the status critical.*
- *Increase trust in the transplant process by improving transparency. Patients will feel empowered because they can see the process.*
- *Create a technology platform that allows us to add future functions. Future functionality may include the reason(s) for labeled inactive (waiting on your labs).*
- *Reduce organ discards by increasing the pool of active candidates. Recovered organs will have more options for a new home.*

The Subcommittee's proposed phone application would allow a candidate or caregiver to initiate a query of their individual status on the wait list (active vs inactive), but not provide alerts related to change in status. A candidate identifier could be distributed by the transplant hospital at the time of listing.

The Subcommittee sought feedback from OPTN staff on how to advance this project, including challenges and limitations.

A HRSA representative shared that the CMS Increasing Organ Transplant Access (IOTA) Model<sup>3</sup> does include requirements for patient notification. He was unsure if this is something that might align with this conversation, recognizing that IOTA is focused only on kidney. He questioned whether this proposed project might leverage requirements for centers involving the IOTA model.

OPTN Contractor staff noted that the proposed solution is unique in that the OPTN does not communicate directly to patients via the OPTN computer matching system. HRSA acknowledged that

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<sup>3</sup> <https://www.cms.gov/priorities/innovation/innovation-models/iota>. Accessed on 9/9/2024

this is something that has not been done before. Current policy limits access to OPTN systems only to OPTN members (OPOs, histocompatibility labs, transplant hospitals).

OPTN Contractor staff discussed potential consideration. Due to the Contractor's preliminary estimates of proposed solution size and scope, and the fact that the proposal is currently a tech-only solution that does not include policy requirements or policy changes, the OPTN Contractor noted that the process for approval may need to deviate from the normal policy development process. The process requires the Policy Oversight Committee (POC)'s review and endorsement before the project is recommended to the Executive Committee for approval.

A Subcommittee member asked if a project estimate could be developed before going to the Board. OPTN Contractor staff stated that cost estimates accompany project proposals sent to the POC for consideration, and the same may be requested by the Board of Directors as part of a preliminary review. OPTN Contractor staff acknowledged this but recognized that the scope of this proposed project is different in that it is not modifications or additions existing computer system but rather developing a new tool that would allow patients to access to the system and the security checks this would require for system safety. Subcommittee members sought information on the overall scope of this effort, as they currently seek to provide candidates with their status on the wait list, active or inactive, but may wish to build upon functionality in the future.

A Subcommittee member asked how the phone application or new tool would be communicated to the patients. Would this require endorsement from individual centers to make them aware of its existence?

OPTN Contractor staff noted that the primary consideration is identity management in accessing the OPTN computer system. OPTN Policy 3.1 *Access to the OPTN Computer System* notes that only OPOs, transplant hospitals, and labs have access to the OPTN Computer System. This policy would have to be updated to allow patients to access this information via the proposed phone application. Other security regulations and laws around protecting patient data would also need to be carefully reviewed. The primary goal here is to ensure that the correct data is being shared with the correct patient. An additional consideration is that neither the OPTN Computer System nor OPTN policy requires collection of unique patient identifying information or contact information that might be used to help establish and validate identity or communicate directly with the patient. New data collection will likely be necessary to facilitate communication and validate identity.

In acknowledging the Subcommittee's concern that some patients may not be aware of their status, and acknowledging the aforementioned considerations that would need to be addressed, a recommendation was made by OPTN Contractor staff to also consider solution alternatives to the phone application. The OPTN already has application programming interfaces (APIs) that allow transplant hospitals to query their waiting list for information in real time, including patient status on the wait list. Many hospitals have websites or phone applications that have already addressed identity management and authorizing patient or caregiver access to medical information. OPTN Contractor staff suggested that this solution may some mitigate project-associated costs, but also potentially add to costs to members, should they need to develop a pathway for their existing patient portals to include candidate wait list status. This alternative enables information being readily available alongside appointment scheduling and lab results-putting it more in context with their overall patient care and providing a more seamless patient experience.

A HRSA representative noted that the OPTN Contractor is required to capture the cost of every project in developing the annual budget. The Policy Oversight Committee and the OPTN Board will prioritize which projects to budget for, based upon resources available for its overall portfolio.

Patient experience was also recognized. Because only transplant programs, as a patient's direct medical care provider, would have the necessary information for the patient regarding what steps would be necessary to transition from inactive to active status, the OPTN is not the appropriate entity to communicate this information. The OPTN does not direct medical care. Subcommittee members were asked if they thought this may be a point of frustration or a barrier to patients when only receiving one piece of information and then having to go to the transplant hospital for further direction. A Subcommittee member noted that the Committee sees this as a novel first step for the OPTN to put this information forward and not have it fall to the transplant centers. A Subcommittee member suggested disparity within transplant centers, with some more forthcoming and robust in their communications than others. Subcommittee members acknowledged that all centers must report this information up to the OPTN as the one repository of this information. The OPTN houses the individual patient information regarding status on the wait list submitted by transplant hospitals. For this reason, the Subcommittee believes it appropriate for the OPTN to provide this information as it stores this information for all transplant hospitals.

Concern for the small percentage of individuals without a smart phone was acknowledged. An alternate pathway such as a phone number may be something to investigate to provide this information in a different format.

The Subcommittee chair acknowledged the size and challenges of the project, reflecting on its request to the Data Advisory Committee for transplant programs to report more patient-specific information (e.g. phone numbers, email addresses, emergency contact information). The Committee was told that this was outside of the scope of work for the current Data Directive effort.

A Subcommittee member noted that it would like to see flexibility in the programming solution that is ultimately developed. The Committee does not want to limit the ability to provide subsequent functionality (beyond wait list status is active or inactive) in the future because the next steps had not been thought through ahead of time in developing this foundation. The Chair noted that some of the other committee leadership he had spoken to was thinking similarly. These ideas will be documented for transparency. OPTN Contractor staff suggested that it is important to think about this potential flexibility now, even if the additional functionality is not initially implemented so that the appropriate foundation can be developed to allow for expansion. Subcommittee members were encouraged to think about the patient experience. Now that a candidate knows that they are inactive, what is the next step? What is the call to action for the user at that point?

Subcommittee members agreed that patients want to understand where they are on the list. A member also noted that more education is needed on what being on the list means (though this is not part of this proposed project. Simply knowing that they are active on the waitlist will be beneficial with simple language telling them to call their transplant hospital if they have questions or need further information. A Subcommittee member shared that a family member did not know they were inactive on the wait list. Subcommittee members acknowledged that likely only a small percentage of patients who are inactive on the wait list are unaware they are inactive. The Subcommittee see providing this information in real time as providing peace of mind during the wait for an organ.

OPTN Contractor staff noted that requiring transplant programs to share this information on whatever cadence convenient for their processes and workflows could be achieved faster than building a new software application. The applications that many hospitals use today are readily available and in use by patients. These applications already have identity management. OPTN also already has the APIs to share this data with them readily available. Currently, centers are not required to share this information with patients. Putting this requirement in policy will mandate its sharing and create a pathway for the OPTN

to manage compliance on this requirement. Transplant programs can explain more to their candidates regarding the reasons why a candidate is in a certain status.

The Subcommittee Chair noted that the 250+ transplant centers all have their own way of doing things. He said this has been encouraged for 40 years. It was also stated that the Committee is not looking for a quick win, but rather does not wish to overly burden transplant coordinators and transplant centers who say they do not have the resources, means, or money to do things. The Chair pointed to the OPTN Contractor as the central repository for this information. The Chair stated that all he felt was needed was a unique customer ED to safely ascertain the wait list status for a particular patient.

OPTN Contractor staff noted that from a compliance perspective, a policy requiring transplant centers to inform patients of wait list status would standardize practice and reduce variability that the Subcommittee Chair referenced. Policy would allow the OPTN to monitor and make sure that this information is being communicated to patients. If a phone application was developed, there may still be the need for a policy requirement for centers to update their patient status. If there is an administrative delay on the transplant center side from moving a patient from inactive to active, the policy requirement could then be used to monitor and support increasing transparency in this area.

A Subcommittee member shared that he believes that transplant centers should be required to notify patients and regardless of the path forward, he does not understand why he would not get a call from his program if his status had changed (though this is not part of the proposed solution at this time). If transplant hospitals are not already doing this, they should be required to do so. While the phone application would be a nice addition, he does agree that a transplant center requirement should be in place, noting that this should be common practice. Another Subcommittee member shared that they were so ill going through the wait for an organ that there were many times they could not understand or focus on what was being said to them. For this member, getting the registered letter saying that they were on the wait list was important to them. Having the app and seeing a simple green (active on waitlist) or red (inactive on the waitlist) would be easier and bring peace of mind.

Discussion then returned to patient identification in sharing sensitive protected health information. Comparisons were made to online banking. OPTN Contractor staff talked about highly sensitive OPTN data carrying the highest risk rating in the Federal system. There are a number of processes to go through before data can be released, and those to whom it is released are under data use agreements to make sure that the data is being used and managed appropriately. Firewall protections and navigating multiple identifiers was discussed in sharing data in the US healthcare system. Information cannot be released to anyone that has the identifier.

The Subcommittee Chair requested HRSA input on whether this project is feasible. HRSA encouraged exploration of all pathways to achieve the goal of ensuring that patients are aware of their current status on the wait list. OPTN Contractor staff reiterated that a policy solution will ensure universal communication to all patients through their transplant centers.

#### **4. Next Steps: Policy Oversight Committee Project Review and Approval**

The Chair thanked all participants for sharing their knowledge and time. He sought commitment to continue to find a way to make this happen in the most cost-effective way possible.

#### **Upcoming Meetings**

September 17, 2024

## Attendance

- **Committee Members**
  - Garrett Erdle, Chair
  - Lorrinda Gray-Davis
  - Michael Brown
  - Cathy Ramage
  - Justin Wilkerson
- **HRSA Representatives**
  - Robert Johnson
  - Mesmin Germain
  - Adrienne Goodrich-Doctor
- **UNOS Staff**
  - Shandie Covington
  - Kaitlin Swanner
  - Desiree Tenenbaum
  - Kimberly Uccellini
  - Rob McTier
  - Nadine Rogers
  - Laura Schmitt
  - Roger Brown