

## Executive Committee Report to the Board of Directors

*Dianne LaPointe Rudow, Chair*

*June 18, 2024*

This report reflects the work of the Executive Committee from December 2023-May 2024. Complete summaries from Executive Committee meetings can be found on the [Executive Committee's webpage](#).

### Overview

The Executive Committee met ten times via teleconference and once in-person since their previous report to the Board. Two of the ten teleconferences were held in closed session. Committee meetings were led by Dianne LaPointe Rudow, Chair, and attended by a quorum of Committee members, along with HRSA representatives and contractor staff.

### New Committee Projects

Since December 2023, the Executive Committee approved initiation of the following committee projects:

Project	Sponsoring Committee
Reduce HLA Critical Discrepancies and Require Reporting to the OPTN	Histocompatibility
Ethical Analysis of Allocating Organs Out of Sequence	Ethics
Requirements for Communicating Post-Transplant Disease	Disease Transmission
Promote Efficiency of Lung Donor Testing	Lung
Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS	Liver & Intestinal

### Public Comment Items

The Executive Committee approved the following items for distribution for [public comment](#) during the winter 2024 cycle:

Public Comment Item	Sponsoring Committee(s)
Update Post-Transplant Histocompatibility Data Collection	Histocompatibility
Update on Continuous Distribution of Hearts	Heart
Modify Effect of Acceptance Policy	Multi-Organ
Concepts for Modifying Multi-Organ Policies	Multi-Organ
Refit Kidney Donor Profile Index without Race and Hepatitis C Virus	Minority Affairs
Standardize Six Minute Walk for Lung Allocation	Lung
Clarify Requirements for Pronouncement of Death	Organ Procurement Organization
Standardize the Patient Safety Contact and Reduce Duplicate Reporting	Disease Transmission Advisory
National Liver Review Board (NLRB) Updates Related to Transplant Oncology	Liver & Intestinal

Promote Efficiency of Lung Allocation	Lung
OPTN Strategic Plan 2024-2027	Executive

## Special Public Comment Items

The Executive Committee submitted approved three special public comment proposals since the last Board report. These public comment items were:

- Expedited Placement Variance
- Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards
- Establish Code of Conduct and Whistleblower Protection Bylaws.

The Expedited Placement Variance was available for public comment in December 2023 to January 2024. This proposal recommended a new variance related to expedited organ placement and proposed modifying the OPTN’s variance process in order to allow for more rapid studies of potential improvement. The Board approved this policy and the policy was implemented on April 2, 2024.

The Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards was available for public comment from December 2023 until February 2024. This proposal furthered the collective desire of the OPTN Board of Directors, HRSA, and the transplant community to separate the OPTN Board and the contractor’s Board and remove any actual or perceived conflicts of interest between the two boards. This proposal was aligned with HRSA's stated objectives in their OPTN Modernization Initiative to "creat[e] an OPTN Board of Directors independent from other OPTN contractors to strengthen accountability and oversight. The proposal removed the requirement that the OPTN Board of Directors be identical to the OPTN Contractor’s Board of Directors and prohibited members of the OPTN Board of Directors from serving as an employee of, or serving on the Board of Directors of, any organization contracted to support the OPTN. The Board approved this policy and it was implemented on March 30, 2024.

The proposal to Establish Code of Conduct and Whistleblower Protection Bylaws was available for public comment from April 2024 to May 2024. The proposal seeks to specifically document and codify existing practices that encourage participation in the OPTN and establish processes and protections within the OPTN Bylaws. The Executive Committee has reviewed public comment and will send the final proposal to the Board to take action on during their June 12 meeting.

## Policy Action Items

### Update Liver Diagnosis Code Nomenclature & Treatment Options for HCC Exceptions

The committee approved data collection modifications from the Liver and Intestinal Organ Transplantation Committee to update diagnosis codes on liver Transplant Candidate Registration (TCR) and Transplant Recipient Registration (TRR) forms to align with current terminology. The proposal also updated HCC initial and extension exception forms to allow for automatic approval of candidates utilizing new HCC treatments that otherwise meet standard criteria.

## Other Committee Work

### OPTN Strategic Plan 2024-2027

The Executive Committee submitted the OPTN Strategic Plan 2024-2027 for Winter 2024 Public Comment. Throughout the winter and spring, the committee met to analyze public comment feedback, make changes to the proposal based on public comment feedback, and then submitted a final recommendation to the Board for their consideration during their June 2024 meeting. The final proposed strategic plan includes four goals:

- Increase opportunities for transplants
- Optimize organ use
- Enhance OPTN efficiency
- Support OPTN Modernization Initiative

The plan includes an introduction to the plan, the OPTN Vision, the four goals listed above, eleven objectives, and twelve metrics. The committee emphasized the importance of the strategic plan to lead OPTN work, and encouraged that in the future the Executive Committee and the Board review progress towards the strategic plan more frequently. Additional detail on the strategic plan can be found in the briefing paper.

### eGFR Waiting Time Modifications Monitoring

The Executive Committee and HRSA directed the Membership and Professional Standards Committee (MPSC) to develop a plan to review kidney programs who submitted an attestation without submitting any or few wait time modifications. The MPSC conducted a data review and determined a threshold of programs with Black/African American candidates registered but submitted modifications for fewer than 20% of those candidates. Letters of inquiry were then sent to these programs, and the MPSC will review cases and determine next steps for these programs.

### Expeditious Task Force

The Executive Committee has received multiple updates from the Expeditious Task Force and their work since December 2023. The Executive Committee has been in close collaboration with the Task Force regarding the Expedited Placement Variance Proposal that was available for special public comment. The Task Force has provided updates to the committee on the expedited placement variance, securing commitments, and their planned upcoming work.

### Data Directive

The Executive Committee continued to discuss the Data Directive from HHS that the OPTN received on February 5, 2024. HRSA requested input on two pre-waitlist forms, aligned with the Data Advisory Committee's (DAC) feedback and form instructions. HHS also requested a ventilated patient form that would combine the two drafted forms HRSA provided. The OPTN expects the 60-day federal notice to be posted in spring 2024 and an OPTN response will be drafted and finalized by the Executive Committee.

## Direction to Analyze MPSC Metrics

During their in-person meeting on March 25, the Executive Committee directed the Membership and Professional Standards Committee (MPSC) to collaborate with the SRTR to consider developing a proposal to increase the threshold for acceptance and to lower the threshold for post-transplant outcomes.

## Peer Review Discussion

During their April 16 meeting, the Executive Committee discussed the MPSC peer review process. The committee discussed how the peer review process is conducted and the importance of confidentiality throughout the peer review process. The committee discussed whether they should be updated on cases undergoing the peer review process, and it was noted that the current process is kept strictly confidential to ensure there is no bias from the committee if the case is brought to the Board for action. The Executive Committee will continue conversations on the appropriate level of engagement from the Board of Directors.

## SARS-CoV-2 Summary of Evidence

The Executive Committee approved updates to the Ad Hoc Disease Transmission Advisory Committee's (DTAC) [SARS-CoV-2 Summary of Evidence](#). The DTAC reviews the summary of evidence at least annually to ensure it is up to date. The updated summary of evidence includes new literature, data, and terminology.

## Mpox Summary of Evidence

The Executive Committee approved updates to the Ad Hoc Disease Transmission Advisory Committee's Mpox Summary of Evidence. Updates to the document include case numbers to show an increase in cases reported in the United States, the CDC's recommendation for a vaccine, and a "Screening Considerations: Deceased Donor Considerations" section.

## Updates to Pathogens of Special Interest

The Executive Committee approved updates to the Ad Hoc Disease Transmission Advisory Committee's [Pathogens of Special Interest Document](#). The DTAC reviews the list annually. The committee added candida auris to the document.

## Offer Filters Implementation Timeline

The Executive Committee approved a change in the offer filters implementation timeline. The Executive Committee approved that the OPTN Contractor was released from their 12-month Service Level Agreement (SLA) with the OPTN Board of Directors regarding the implementation of *Optimizing Usage of Offer Filters* proposal, in order to prioritize the implementation of the *Enable Liver Offer Filters* project and the *Enable Heart Offer Filters* project.

## Letter from the UNOS Xenotransplantation Work Group

The Executive Committee received a letter from the UNOS Xenotransplantation Work Group that identified questions that the OPTN needs to answer by the time xenotransplantation becomes a common therapy for organ failure. The committee considered different ways to approach the impact of xenotransplantation on the OPTN. As a result, the OPTN Ethics Committee prepared a memo regarding ethical considerations in the determination of waitlist status and deceased donor organ allocation for xenotransplantation clinical trial candidates and recipients.

## Code of Conduct Work Group

The Executive Committee developed a Code of Conduct Work Group to codify a Code of Conduct and Whistleblower Protections for OPTN volunteers. The Work Group met six times since December 2023 to develop a proposal for special public comment. After special public comment, the Executive Committee will consider public comment feedback, and will submit the final proposal to the Board to take action on during their June 12 meeting.

## Prioritization Work Group

The OPTN Prioritization Work Group was developed in February 2024 to focus on refining the current OPTN prioritization process. This refinement aims to enhance the review and reprioritization of the active work of the OPTN, to increase transparency into the prioritization process, to incorporate the work of the Expeditious Task Force into the prioritization process, and to aid in the allocation of resources to pursue a more focused OPTN strategic plan. The work group's goal was to provide recommendations for Board consideration regarding the overall prioritization process. Emerging themes included resource analysis, consistency, visibility, and communication.

Key focus areas of the work group's efforts include idea intake and generation, early prioritization (prior to the Policy Oversight Committee's (POC) new project review in the existing process), strategic plan goal alignment, and clarity of roles and responsibilities.

The work group discussed idea generation and intake, recognizing a desire to consider ideas from all sources, including patients, societies, the public, committees, task force, etc. At this time the work group recommends that ideas from the task force and ideas generated for the strategic plan at the direction of the Board or Executive Committee be included in the project tracking dashboard and be included in the prioritization process to address visibility and transparency. The work group recommends the refinement of an OPTN dashboard to display ideas and project status and to expand the scope of the dashboard.

The next key focus area was early prioritization, prior to POC's new project review in the existing process. The work group proposes the further development of an idea intake rubric for committees to use. This rubric would utilize similar attributes to rubrics later in the process, allowing for new ideas to be compared to the ongoing work of the OPTN. The work group also proposes the implementation of a quarterly portfolio review process, where the work of the OPTN at various stages of development and resource planning can be compared and the priority level of work can be adjusted if needed. Following

the portfolio review and prioritization process, the work group recommends broad visibility and communication of prioritization to the Board and Committees.

The work group considered the proposed strategic plan and sought guidance from the Executive Committee on interpretation of the goals and plan. In recognition of the more focused nature of the goals, both the work group and the Executive Committee recommend a pathway for priority projects that do not align with the strategic plan goals but do align with the overall mission and vision of the OPTN. The work group recommends alignment to strategic plan goals be incorporated into the prioritization rubrics.

The work group utilized their process recommendations to then consider key characteristics needed for successful execution of the portfolio prioritization process. They then considered those characteristics, the current OPTN structure, OPTN bylaws, and OPTN contract requirements; ultimately determining the POC to be the ideal group to continue managing the prioritization of the OPTN portfolio of work. The work group recommends the addition of Board members with specific expertise to the POC. These additional perspectives will aid in managing the OPTN portfolio prioritization and the recommended additional responsibilities of the POC.

#### Summary of Work Group Recommendations:

- Introduction of an idea screening rubric for committee use.
- Refinement of rubrics utilized throughout project development to provide valuable information for portfolio reviews.
- Introduction of a routine Portfolio review and prioritization process considering new ideas and active work of the OPTN.
- Inclusion of strategic plan goal alignment into rubrics.
- Tracking of idea source to determine benefit vs cost to implement idea intake form in the future.
- Communication of existing idea intake process to community.
- Add ideas to project dashboard for greater visibility.
- Add additional Board representation to the POC.
- POC responsibilities updated to include OPTN Portfolio management.
- Implement defined Board updates on prioritization.