

# OPTN Board of Directors Meeting Summary

## Meeting Information: Agenda and Attendees

Thursday, July 17, 2025 | 1:00–3:00 p.m. ET | Location of Event: Zoom

The following are meeting minutes from the OPTN Board of Directors meeting, which took place on **July 17, 2025, 1:00–3:00 p.m. ET**.

### Agenda

#### Closed Session

- The Board met in a closed session.

#### Open Session

- Finance Update
- Legal Updates for INVEST Insurance
- Network Operations Oversight Committee (NOOC) UNet Update
- Continuous Distribution
- Allocation Out of Sequence (AOOS) and Normothermic Regional Perfusion (NRP) Directives
- Adjourn

### Attendees

Attendee Name(s)	Affiliation
John Magee (President), Shelley Hall (Vice President), William (Bill) Ryan (Vice President of Patient Donor Affairs), Alan Reed (Treasurer), Justin Wilkerson (Secretary), Gina Marie-Barletta, George Bayliss, Jen Benson, Vincent Casingal, James Cason, Kenneth Chavin, Ari Cohen, Andrew Courtwright, Ryan Davies, Meelie DebRoy, Nahel Elias, Samantha Endicott, Gitthaline Gagne, Joshua Gossett, John Hodges, Mary Homan, Darren Lahrman, Kevin Lee, Dan Meyer, Cathi Murphey, Annette Needham, Peter Nicastro, Robert (Cody) Reynolds, Austin Schenk, John Sperzel, Mark Wakefield, Kymberly Watt	OPTN Board of Directors
Aitebueme Aigbe, Brianna Doby, Mesmin Germain, Stephanie Grosser, Frank Holloman, Raymond Lynch, Nolan Simon	HRSA Representatives
Christine Jones, Rachel Shapiro, Vanessa Amankwaa, Thomas Barker, George Barnette, Melanie Bartlett, Tamika Cowans, Lori Downing, Jadyn Dunning, Karen Edwards, Emily Elstad, Rebecca Fritz, Surakshya Karki, Tessa Kieffer, Mona Kilany, Mary Lavelle, Andrew London, Taylor Melanson, Eliana Saltares, Christina Sledge, Zulma Solis, Kristen Welker-Hood	OPTN Board Support Staff

Attendee Name(s)	Affiliation
Ryutaro Hirose, Roslyn Mannon, Jon Snyder,	Scientific Registry of Transplant Recipients (SRTR)
Lauren Mauk, Kim Uccellini, Sara Rose Wells	OPTN Operations Contractor Staff

## Meeting Summary

### *Closed Session*

The Board met in a closed session.

### *Open Session*

The OPTN Board President (“President”) welcomed attendees to the meeting. A Board member shared a tribute to Charles Bearden, a long-practicing transplant coordinator and pioneer in the transplant community who recently passed away.

### *Finance Update*

The Board Treasurer (“Treasurer”) presented a finance update to the Board. The Treasurer and the President met with the previous Treasurer and the Operations Contractor to better understand the OPTN finances and Board responsibilities.

The Treasurer explained the funds in the OPTN budget versus HRSA Modernization funds; the Board makes recommendations for and approves the OPTN budget, but does not control it. The OPTN budget includes all OPTN operating expenses that are currently being paid to UNOS including:

- Management of the allocation system
- Policy Development/Implementation/Monitoring
- Membership and Professional Standards Committee (MPSC) and other critical committee activities
- Committee work
  - On-site visits
  - Member services
- Communication support
- Any other HRSA directed activities

The Treasurer shared that the Board can recommend but not set the registration fee which ultimately drives the OPTN’s finances. The U.S. Department of Health and Human Services Secretary has the authority to set the registration fee. HRSA ultimately has fiduciary responsibility over the OPTN budget; the Board does not advise HRSA on federal spending and contracts.

The Treasurer shared information about OPTN budget:

- The previous Board requested to increase the registration fee from \$868/registration in FY25 to \$916/registration (5.5% increase) for FY26.
- Draft Investments include:
  - Operating Reserve (historical): Per HRSA's directive, OPTN spent down the \$10 million in the operating reserve over the last three years; there is no excess money available.
  - Required Reserve (per OPTN Bylaws; also referred to as the investment account): the OPTN must have three months of operating expenses cash on hand based on the fiscal year. The current expenses are approximately \$5-6 million per month, and the current budget is \$19 million.
- The critical issue impacting the budget and use of funds for operations are legal fees
  - Estimated Glomerular Filtration Rate (eGFR) lawsuits; unknown impact of Allocation Out of Sequence (AOOS) on future legal costs
- The FY25 Budget surplus is estimated at \$1 million. The Board will continue to receive monthly updates on the FY25 numbers.
- The OPTN is not permitted to accept in-kind donations or other donations to increase revenue.
- The previous Board made the following resolutions regarding FY25 Cost savings:
  - Pausing virtual site visit surveys in the fourth quarter of FY25: net savings of \$110,000
  - Discontinuation of on-critical meeting support for committees without active projects (with the exception of PAC in the fourth quarter of 2025): net savings of \$30,000.

The Treasurer shared the FY25 Budget overview for the Board to review the different categories of expenses. The Treasurer noted that the highest category is personnel expenses, followed by technology and information technology (IT) and legal and litigation costs. The Treasurer shared the previous Board met and voted to approve the FY26 proposed budget and registration fee on 6/20. The budget was proposed by the Finance Committee with recommendations to increase the registration fee to \$916/registration.

The Treasurer shared an overview of the FY26 budget. He stated that personnel costs have increased due to the cost of living and merit increases in FY26, and vacancies that are expected to be filled. Meetings and travel costs have decreased by more than half due to a resolution that was passed by the previous Board. Purchase services (e.g., additional litigation costs for support), and technology and IT have increased. The total expenses for the FY26 budget is \$74,522,805. The Treasurer has not yet been notified of whether the request for an increase in the registration fee has been approved.

A representative from HRSA confirmed that they received the registration fee increase request by the 6/20 deadline from the Operations Contractor and are reviewing it; HRSA will provide a response before FY26 begins.

A Board member asked if there is a possibility to increase the appropriations from Congress. A HRSA representative shared that \$6.5 million in appropriations goes to the Operations Contractor as part of the budget that the Board votes on. The representative explained that HRSA appropriations are also being allocated to many more things for the OPTN (e.g., the Board Support contract, the OPTN Executive Director contract, funding for the Scientific Registry of Transplant Recipients (SRTR), etc.). The newly

allocated items were previously covered within the budget, but are now being funded by appropriations.

A Board member asked, in light of HRSA contracting with 14 contractors, if there are other sectors in which they could find cost savings. A HRSA representative clarified that there are not 14 contractors where there used to be one; that is not the current structure for OPTN contractor support. The Board requested a review of IDIQs during Board Office Hours to provide more clarity on government contracting.

### ***Legal updates for INVEST insurance***

A legal representative from the Board Support Contractor shared that they are in the final stages of renewing the INVEST insurance and expanding coverage for Committee or Workgroup volunteers.

While there is no way to guarantee that a Director or Committee or Workgroup volunteer will not be sued, certain risk mitigation strategies and the structuring of certain insurance coverage will likely result in the prompt dismissal of any lawsuits or minimal damages.

Generally speaking, Directors acting with care and in the interest of INVEST/OPTN are shielded from liability because of the Business Judgment Rule. Directors who engage in misconduct, gross negligence, or who breach their duties may be held personally liable for their actions.

To guard against potential liability, Directors should regularly attend meetings, stay informed (e.g., review OPTN Bylaws), make well-informed decisions, follow the law, act in support of the mission and governing documents, and avoid or disclose any real or potential conflicts of interest.

Delaware state law and Federal law also offer other protections for Directors or Committee or Workgroup volunteers, including the Volunteer Immunity Statute, certain types of insurance coverage, and indemnification provisions.

Directors or Committee or Workgroup volunteers should be mindful of their actions and decisions and ensure that they are performing their roles suitably.

### ***Network Operations Oversight Committee (NOOC) UNet Update***

A HRSA representative provided an update on the NOOC UNet. In December 2024, the previous Board voted for an update to the use of DonorNet that's intended to improve the security of the system, and restricts the use of real time access, or data to cases where an individual identifiable transplant is being performed. In March 2024, the Board decided that two use-cases that were not covered in the policy as it was voted on in December should be included. The first use-case is when there is a multicenter trial and a coordinator at one hospital center who needs to be able to access an organ that is being allocated to a second center; under a strict interpretation of the new policy this case would not be allowed. The second use-case encompasses third parties who contract with organ procurement organizations (OPOs) to make the best use of organs that are donated for the purposes of research, which would not meet be allowed under a strict interpretation of the policy. The Board determined that both cases were valid uses of the data and important to the integrity of the system. The Board voted for a 90-day extension, and HRSA recommends that the Board extend that extension until the NOOC is reestablished and work on the details of putting data use agreements into place.

The Board President shared that the Board Officers endorse the idea of advancing this motion to the Board to support.

The Board voted on the following action:

**WHEREAS**, on March 20, 2025, the Board approved the implementation of the Revise Conditions for Access and Reporting Privacy Incidents to the OPTN Computer System policy as scheduled on March 27<sup>th</sup> and deferred the implementation of permissible use of access to data system for 90 days to allow research to continue with the ability to revisit another deferment if policy update is not completed.

**NOW, THEREFORE, BE IT:**

**RESOLVED**, that with respect to the implementation of the Revise Conditions for Access and Reporting Privacy Incidents to the OPTN Computer System policy, the Board hereby approves deferring the implementation of permissible use of access to the OPTN data system for an additional 90 days to allow research to continue with the ability to revisit another deferment if policy update is not completed as contemplated.

Final Vote: 27 approve, 0 reject, 0 abstain.

### ***Continuous Distribution***

A HRSA representative shared that continuous distribution is a network of policies across the different organ types that has been implemented for the lung in March 2023, and is slated to be implemented for other organs. In light of the critical comment, HRSA determined that it is prudent and responsible to currently pause the work on continuous distribution to ensure that new AOOS policies are effective, evidence-based, and ensure fairness in the OPTN allocation system. The Lung project, which is already in place for continuous distribution, needs adjustments in order to improve its functionality; that work will continue. However, there is a temporary pause for new work until HRSA can ensure that the AOOS work is able to inform all the policies.

A Board member suggested that the work on continuous distribution continue through the fourth quarter of FY25. Many other Board members agreed that it is not advisable to pause continuous distribution. One Board member stated that AOOS is the biggest concern in the transplant community. She agreed that each organ needs to be looked at and that may not be reasonable to have kidney continuous distribution while they're trying to address AOOS. A Board member stated that new Board members have heard many concerns about this issue, as the continuous distribution pause was announced the same day as the new Board was announced. The Board President clarified that the continuous distribution work will not be disbanded; it will be paused. He stated that it will be critical to message the pause appropriately.

A Board member asked if the Board would be able to proceed with continuous distribution in parallel with addressing AOOS. Another Board member noted that the expertise of the Board should be valued. She asked whether there are other items that could be paused to allow for the continuous distribution work to continue.

A Board member asked why the previous Board was asked about pausing continuous distribution while the current Board was told rather than asked. HRSA agreed that the expertise of the Board is critical, and that resources are critical to the function of the organ transplant system. The previous Board did not vote on this issue; they held a statement of sentiment. HRSA reiterated that continuous distribution and AOOS are priorities for HRSA, and that HRSA would like to continue this work in the most sound and most fiscally responsible way possible.

A Board member asked how a pause is defined; HRSA stated that it is not defined by time, but instead by progress. HRSA noted one of the functions of the OPTN is to create a matching algorithm for policy adherence; the critical comment has shown that, using the new definition, there is currently a high degree of non-compliance with the algorithms.

### ***HRSA Directives: Allocation Out of Sequence (AOOS) and Normothermic Regional Perfusion (NRP)***

HRSA provided an update on the response to HRSA Directives on Allocation Out of Sequence (AOOS) and Normothermic Regional Perfusion (NRP).AOOS

The AOOS critical comment was published in September 2024. HRSA received a consensus definition of what is classified as policy non-compliance in AOOS on 6/3 and approved it on 6/6. HRSA responded to the OPTN's proposed AOOS Remediation Plan on 7/10 and met with Board and OPTN Committee leadership shortly thereafter. HRSA expects to receive the new AOOS workgroup composition on 7/18; however, they are flexible with that timeline in order to ensure that there is the best Board and committee representation in the workgroup.

The upcoming AOOS activities are exciting work for the OPTN; it is not siloed committees, it will include the use of agile principles and leveraging asynchronous technology. HRSA plans to frequently report the AOOS workgroup's progress to the OPTN.

The Board President stated that the goal is to ensure that there is appropriate representation from committees in the workgroup. He asked the Board support contractor to provide relevant webpage links to the Board as needed.

### ***NRP***

HRSA provided a brief update on NRP to the Board. Key points from the discussion include:

- The plan to complete the following actions was submitted to HRSA on 4/30:
  - Propose OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations using NRP in patients from whom organs may be procured
  - Propose OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured
- HRSA has done an extensive review of the plan and will provide feedback on to support system improvement and ensure appropriate safeguards for patients.

HRSA stated that there was no recommendation for OPOs to pause NRP while data was being gathered. HRSA clarified that the discovery contractors are funded by appropriations, not operating expenses.

### ***Closing Remarks***

The Board President thanked the Board of Directors for their engagement, and adjourned the meeting.