

**OPTN Executive Committee
Meeting Summary
July 20, 2023
Webex**

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, Chair

Introduction

The OPTN Executive Committee met via Webex on 07/20/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Committee Orientation
3. Board Independence Plan
4. Summer 2023 Public Comment Items*
5. Recap on Strategic Plan from June Board Meeting

The following is a summary of the Committee's discussions.

1. Welcome and Announcements

Dianne LaPointe Rudow, Chair of the Executive Committee, welcomed the committee to the meeting and presented the agenda.

2. Committee Orientation

Susie Sprinson, Board Relations Manager, presented on committee orientation. Ms. Sprinson presented the work the committee has completed over the last six months and how these projects relate to the ongoing work of the committee. The committee was briefed on where to find meeting materials and how they will be notified of these materials.

Ms. Sprinson shared some of the key committee work since December 2022, and how the committee will be asked to continue some of these projects moving forward. The committee will focus on developing the next strategic plan, supporting the POC to maintain alignment with the strategic plan and strategic policy priorities, and to plan for the separation of the OPTN Board and the OPTN Contractor Board of Directors.

Summary of discussion:

A representative from HRSA commented that the plan to separate the Boards was a task for the contractor, and wanted to know what the Executive Committee's involvement in the plan would be. Mr. Jason Livingston, General Counsel, explained that the purpose of today's discussion is to share information with the Executive Committee, who will be charged with implementing the plan. A committee member commented that the plan that comes from HRSA to separate the Board impacts the Executive Committee because they will be charged with implementing the plan and appointing the Executive Director. They stated that they were thankful for the dialogue ahead of time, with the understanding that the plan could change.

3. Board Independence Plan

Mr. Livingston presented on the proposed plan to separate the OPTN Board of Directors and the OPTN Contractor Board of Directors. Mr. Livingston explained that the plan to separate the Boards is a new

OPTN contract task deliverable. The contractor submitted their proposed separation plan to HRSA on July 14, and HRSA will review the plan and provide feedback to the contractor. Once feedback is received, the contractor will have 10 days to incorporate any feedback from HRSA and submit a revised plan. Mr. Livingston noted that the OPTN Board of Directors will also be consulted on the plan, particularly on how they will be involved in the separation and implementing the changes.

Mr. Livingston explained that there are twelve different requirements the plan must meet, as set by HRSA. Some of these requirements include how to address potential liability of officers and directors, or what the relationship between the OPTN Board of Directors and the OPTN Executive Director may look like. Mr. Livingston explained that some of the requirements were more difficult to address as there are still many contingencies and unknowns.

Mr. Livingston presented on how these relationships will need to be adjusted when the plan is implemented. The current contract states that the OPTN Contractor's Board of Directors will serve as the OPTN Board of Directors, only for the duration of the contract, and are limited to the terms of the contract. This current model designates the current contracting organization as the OPTN and the OPTN Contractor's Board as the OPTN Board. Mr. Livingston explained that because the contractor's Board serves as the OPTN Board, this is how directors and officers are protected under a shield of liability, as they are considered part of the contractor's corporation. Mr. Livingston also explained that currently, the contractor is permitted to collect the OPTN Registration Fee as their funding for the cost share contract. The contractor may also maintain a reserve and operating account on behalf of the OPTN. Mr. Livingston explained that the OPTN Bylaws states that the Executive Director of the OPTN is an employee of the contractor, and thus is how the Executive Director has the authority to direct actions of contractor employees. The day-to-day details of the OPTN and OPTN Contractor's oversight are written in the OPTN Contract; although the OPTN is a private nonprofit entity in the statute, its' activities are constrained by the contract. Mr. Livingston explained that in separating the Board's, it is important to consider how to rebuild relationship and connections, and establish the authority, accountability, and responsibility of the OPTN and the OPTN Contractor.

Mr. Livingston shared the proposed separation plan that had been submitted to HRSA by the OPTN Contractor. The proposal suggests incorporating the OPTN as a separate entity. With the OPTN as a separate entity, this would comply with the Final Rule and would provide a limited liability shield through the corporate structure for volunteer officers and directors. The proposal also included suggestions on ways to build connections between the OPTN, the OPTN Contractor, and HRSA. These suggestions included having the "new OPTN" hold a contract with HRSA to be "designated" as the OPTN, which would be consistent with the OPTN Final Rule and states that the Secretary designates an organization to be the OPTN. It was noted that the contract would need to define which organization, HRSA or the OPTN, is responsible for different functions. Another suggestion in the proposed plan is for the OPTN Executive Director to be a contractor to the new OPTN, and not an employee of the contractor. Because the new OPTN has no employees and an undefined role for the Executive Director, it would be inappropriate for the OPTN to hire a full-time Executive Director as its only employee. The contractor's plan suggests that the OPTN retain a fractional Executive Director that meets the needs and expectations of the OPTN Board of Directors and would be directly accountable to the Board of Directors of the new OPTN.

Mr. Livingston presented on key assumptions for separating the OPTN Board from the OPTN Contractor Board and the current state of their relationship. The goal is to have the OPTN as a separate entity and the Boards independent from one another by the end of the current contract period. The contractor's proposed plan was developed under the assumption that the current OPTN Policies and Bylaws will govern the OPTN and be substantially the same as they currently are. Mr. Livingston explained the OPTN

Charter and how this will also need to change as the Boards become independent from one another, however he suspects policies will be largely unaffected. Mr. Livingston stated that there will need to be an understanding between the OPTN and the government when it comes to policy adoption due to provisions set forth in the Final Rule.

Although there is not currently an agreed upon timeline, the contractor has included a suggested timeline in their separation plan. Mr. Livingston explained that these are key activities that must happen in the proposed order, but the dates at which they occur are more flexible. First, the contractor suggested that HRSA provide feedback on the plan to the contractor, 10 days after submission and have HRSA provide a revised plan to the contractor. Then, HRSA must approve an independence plan and grant authorization to the contractor to implement the plan. The current Board of Directors must agree to serve as the new OPTN Board of Directors and submit written confirmation that they will serve as the initial directors of the new OPTN Board. Next, an organizational meeting of the new corporation must be held and they must submit filings of the articles of incorporation to form the new entity to the State Corporation Commission (SCC). Next, an organizational meeting must be held with the new OPTN Board of Directors to adopt the OPTN Bylaws, appoint an Executive Committee, and elect corporate officers and an Executive Director. Although this may be viewed as a formality, it is vital that the Board adopt the OPTN's Policies and Bylaws. Next, the new OPTN entity must obtain confirmation from existing OPTN members that they would like to become a member of the new OPTN corporation. Educational components will be necessary when informing members of this change. Mr. Livingston specified that endorsement from the OPTN Board of Directors is vital, as they will be the group tasked with implementing the approved separation plan.

Summary of discussion:

A representative from HRSA stated that the contractor was asked to submit a separation plan and was not asked to propose a timeline or proposed implementation. Mr. Livingston responded that the contract deliverable required the contractor to lay out a timeline with proposed milestones to incorporate the organization and that the timeline is part of the contractor's suggested plan. He stated that there has been no direction from HRSA to implement this plan, but stressed that having a plan in place soon is crucial. The representative from HRSA responded that the timeline is important to see how this would be implemented, but that HRSA's main focus is patient safety and making sure the Board continues service to the transplant community.

A representative from HRSA asked that if the contractor's proposed plan was approved and implemented, whether the contractor would do so without a budget change and whether this would be implemented under the current proposed six-month contract extension. Mr. Livingston explained that the cost of implementation would be covered under the present Board support tasks, and that the largest cost would likely be on outside counsel. Mr. Livingston stated that the contractor will not implement a plan until it is directed to do so by HRSA. Dr. Maureen McBride, Executive Director of the OPTN, stated that the contractor will need feedback from HRSA to determine whether there will be a budgetary impact, as no budgetary impacts have been assumed by the contractor at this time. Dr. McBride stated that it is important to have an approved plan in place first to evaluate the timeline and analyze whether the plan can be incorporated within the contract extension period.

A committee member asked about confirming membership from existing OPTN members into the new OPTN, and whether there is a scenario where members may choose not to join the new OPTN and potentially fragment the system. Mr. Livingston explained that the Centers for Medicare and Medicaid Services (CMS) require that Organ Procurement Organizations (OPOs) and participating hospitals abide by the rules and requirements of the OPTN in order to participate in Medicare. Therefore, members choosing not to join the new OPTN is theoretically possible, but very slim because it is impractical for

members to do. A representative from HRSA commented that they will discuss these potential changes with CMS.

A representative from HRSA asked whether the cost to protect OPTN volunteers from legal liability was included in the plan from the contractor. Mr. Livingston explained that because the new OPTN would be an entity it would have its own money, own liability position, own insurance, it could be sued in its own name, could own property, and can have employees under its own entity. Mr. Livingston explained that these are areas where it will need to be determined whether these functions are met through a series of subcontractors or whether the new OPTN will hire its own staff. Dr. McBride explained that any expenses that the OPTN incurred to ensure directors would begin when the new OPTN is created.

A representative from HRSA asked for clarification on how the OPTN would cease to exist after the contract period. They explained that to their understanding, at the end of the contract period, the contractor would cease acting as the OPTN, and the OPTN would maintain itself independently. Mr. Livingston explained that it is correct the OPTN would cease to exist because the OPTN is not currently an entity and has no legally recognized existence. Making the OPTN an entity would give it a legally recognized existence as a corporation, presumed to have a perpetual duration and have the rights and responsibilities of an entity. Once the contractor ceases to serve as the OPTN, then officers and directors of the Board of Directors would not be part of a corporate entity anymore and would not have a corporate shield from liability and each could be sued in their individual capacities.

A representative from HRSA asked if this is the only plan the contractor suggests. Mr. Livingston explained that the proposed plan is very similar to the plan the contractor suggested to HRSA a few years ago in order to meet the parameters of the statute and regulation that the OPTN is a private nonprofit entity. Mr. Livingston stated that there are multiple ways to structure the relationships between the multiple contractors, the government, and the OPTN, but the contractor does not see another solution that adheres to the parameters of the statute. Mr. Livingston noted that the contractor has confirmed this plan with outside counsel.

A member of the committee commented that this handoff must be well planned in order to protect the volunteers, while also ensuring the work of the OPTN continues.

A representative from HRSA stated that the OPTN Board may provide feedback on what type of individual they foresee serving as the OPTN Executive Director. They stated that this is an area that the OPTN Board of Directors could start thinking about, even without a confirmed plan in mind. The representative said that the OPTN Board of Directors can deliberate on the roles and responsibilities of the OPTN Executive Director, because there is nothing in the OPTN Bylaws that outlines the duties of the Executive Director. A committee member replied that this is something the OPTN Board could be involved with and that there are important parts of the Executive Director role that must be noted ahead of creating the OPTN as its own entity. For example, the committee member noted that if there are subcontractors that the OPTN uses as staff, this raises the question of who is responsible for managing these subcontractors. Another committee member commented that without knowing the supporting infrastructure of the new OPTN, it is almost impossible to start to think of the Executive Director's job description. They explained that the change of the OPTN is much larger than just the Board and there are many other OPTN volunteers that will be affected by this change.

A representative from HRSA replied that this presentation has highlighted that there is much more work to be done. Another representative from HRSA stated that because there is a lot more for the government to complete when it comes to creating a separate OPTN, this is why they did not ask for an implementation plan in the contract deliverable. A committee member asked what would happen if a

plan is not implemented by the end of the contract period. A representative from HRSA explained that they do not currently know who the next contractor will be.

A committee member suggested that it could be helpful for the Board to look at the division of the OPTN and the OPTN Contractor and study some of the professional societies members are part of as guidance.

4. Summer 2023 Public Comment Items*

Jennifer Prinz, Chair of the Policy Oversight Committee (POC), presented the summer 2023 public comment items. Ms. Prinz explained that the committee first discussed and previewed the items for public comment on May 8, and met on July 19 to take a final vote on the items. It was noted that during the May 8 meeting, there was a focused interest from the committee on the Kidney-Pancreas Continuous Distribution timeline and the normothermic regional perfusion (NRP) proposal's stakeholder engagement. During the July 19 meeting, the POC's discussion focused on the proposal to Modify Organ Offer Acceptance Limit from the Organ Procurement Organization (OPO) Committee and the NRP proposal from the Ethics Committee.

Ms. Prinz explained that the POC is asked to focus on specific questions when evaluating the policies to determine whether individual committees have done their due diligence in their policy development work. Committee members are asked to consider whether the proposal addresses the purpose of the project, if the proposal sufficiently explains the reasoning and provides sufficient evidence for the solution, whether appropriate stakeholders were engaged, and if there are any questions that should be included for community feedback that are not already identified in the proposal. The POC is then asked to consider whether the proposed policies are ready for the Executive Committee's consideration for public comment.

The committee first heard the proposal from the Organ Procurement Organization (OPO) Committee to Modify Organ Offer Acceptance Limit. The purpose of the project is to reduce the limit for simultaneous organ offer acceptances for a single candidate, per organ type, from two to one. The POC voted in approval of the project. POC members who did not vote in approval represented individual organ specific committees that were challenging whether the offer process should be limited to a single offer for the candidate, and not whether the policy is ready for public comment.

The White Paper on the Ethical Analysis of Normothermic Regional Perfusion (NRP) from the Ethics Committee was discussed next. The purpose of the white paper is to analyze the implications of normothermic regional perfusion (NRP) according to nonmaleficence (do no harm), respect for persons, and utility. Ms. Prinz noted that there was collaboration from multiple committees and organizations on the project. The final vote from the POC was 12 yes, 2 no and 2 abstain. Ms. Prinz noted that the two declining votes were largely related to the conversation around portions of the ethical analysis and whether members of the POC agreed with the practice. Overall, the POC agreed the information is important to distribute to the community, so the OPTN may receive public comment and improve the NRP process as a result of public comment.

The remaining items being submitted for summer 2023 public comment were presented to the committee. The Heart Transplantation Committee's project to Amend Adult Heart Status 2 Mechanical Device Requirements seeks to modify the heart allocation policy to require certain proof of inotrope failure within 7 days prior to the use an Intra-Aortic Balloon Pump (IABP) in order to gain status 2 ranking. There was discussion and full approval from the POC to recommend the project to the Executive Committee for public comment. Concepts for a Collaborative Approach to Living Donor Data Collection from the Living Donor Committee was presented. This item considers solutions to fill gaps in

knowledge regarding long-term outcomes and barriers to living donation. There was unanimous approval from the POC to recommend the project to the Executive Committee.

The Continuous Distribution of Livers and Intestines Committee Update from the Liver and Intestinal Organ Committee was unanimously recommended by the POC. This item provides an update on liver continuous distribution and supplement the values prioritization exercise. The proposal from the Operations and Safety Committee (OSC) to Collect Donor CRRT, Dialysis, and ECMO Interventions Data was also unanimously recommended, this item seeks to create a multi-option field within the OPTN Donor Data and Matching System that standardizes the reporting of donor continuous renal replacement therapy (CRRT), dialysis, and extra-corporeal membrane oxygenation (ECMO) interventions. The proposal from the Membership and Professional Standards Committee (MPSC) to Require Reporting of Patient Safety Events, which seeks to require the reporting of near misses in OPTN Policy, was unanimously approved to move forward. Ms. Prinz noted that the MPSC received feedback from the Patient Affairs Committee (PAC) about the importance of this process moving forward. The Histocompatibility Committee submitted a proposal to Update HLA Equivalency Tables 2023 to increase the efficiency of unacceptable antigen screening for sensitized candidates by increasing the granularity of HLA typing and unacceptable antigen options in the OPTN Computer System, which is a required proposal for the Committee to submit. The second proposal from the Histocompatibility Committee is to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates. The proposal looks to remove additional documentation for kidney candidates whose calculated panel reactive antibodies (CPRA) score is 99-100% to delay them gaining allocation priority. The POC unanimously approved both items from the Histocompatibility Committee.

The Disease Transmission Advisory Committee (DTAC) submitted a guidance document to Improve Donor Evaluation for Endemic Diseases Guidance Documents Revisions that aims to update and consolidate documents on the OPTN website for endemic diseases and was unanimously approved by the POC. The DTAC also submitted a concept paper on the Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results that aims to clarify OPTN Policy on deceased donation from HIV positive donors. A guidance document from the Vascularized Composite Allograft (VCA) Committee to Update Guidance on Optimizing VCA Recovery from Deceased Donors that aims to provide guidance to transplant programs and OPOs on VCA recovery from deceased donors was unanimously approved by the POC. It was noted that the OPO Committee in particular is supportive of this guidance document.

The POC analyzed an update on the Continuous Distribution of Kidneys and Pancreata to update the community on KP continuous distribution work that includes decisions on attributes, rating scales and modeling results. The POC also analyzed the Continuous Distribution of Hearts Concept Paper to update the community on heart continuous distribution work identifying attributes. The POC unanimously approved both continuous distribution projects.

The summer 2023 public comment items were all presented based on which strategic plan goal they fell into.. The total of implementation resources were also presented to the committee, where a gap between the planned hours and actual hours was noted. It was explained that this gap is due to the delay of kidney-pancreas continuous distribution and the POC is currently analyzing other operational updates and other continuous distribution work that could take place during this period to utilize this gap in implementation resources.

Summary of discussion:

A representative from HRSA asked whether there have been any modifications to the proposals since the POC met on July 19. They also asked what the difference is between a white paper and policy

proposal. Dr. Andrew Flescher, Chair of the Ethics Committee, noted that the committee has made recent changes to the proposal that do not require a vote, however per OPTN Bylaws, the committee was not permitted to make substantial changes to the policy without a vote, therefore no substantial changes have been made since the POC met on July 19. A committee member asked about the process an OPTN White Paper follows. Dr. LaPointe Rudow explained that white papers are submitted for public comment, then after public comment the paper will be sent back to the Ethics Committee to incorporate feedback, then the proposal will go to the Board of Directors. The Board will take the final vote on whether the white paper will be disseminated out to the community. White papers are an ethical analysis, not a policy. After the paper has gone through the public comment process then other committees can decide whether policies should be developed based on the analysis of the paper. The Ethics Committee was praised for their work and for addressing the controversial topic in an appropriate manner.

A committee member asked if there were any donor family members that were part of the NRP workgroup that helped create the paper. Ms. Prinz responded that donor family feedback was received throughout the development of the paper.

Vote:

The OPTN Executive Committee unanimously approved the items for Summer 2023 public comment.

5. Recap on Strategic Plan from June Board Meeting

Trish Jasion, Strategic Operations Service Line Leader, presented a recap on the strategic planning process and feedback that was collected during the June 2023 Board meeting.

Ms. Jasion shared themes of the feedback received during the June 2023 Board meeting, and how these themes were compiled to address different priorities identified by the Board. The five key themes that were identified were:

- Patients: engagement, education and transparency,
- Increase transplants
- Increase donors and available organs for use
- Maximize value of organs/increase post-transplant quality of life
- Improve allocation efficiency

These themes were shared with the committee as a starting point to discuss how to move these ideas and mold them into goals. The Executive Committee will soon begin drafting the goals, drafting potential metrics, and they will start to define key initiatives to achieve key metric results. The next step in the overall process map is that the OPTN will collect community feedback starting in August at regional meetings to gain more insight from key stakeholders.

Summary of discussion:

A committee member asked about next steps for the Executive Committee after regional meetings and how the committee will narrow down the goals and feedback to create meaningful metrics. Staff responded that the Executive Committee will continue their discussions about the strategic plan throughout their summer and fall meetings.

Next Steps:

The Committee was asked to review all feedback received during the June 2023 Board meeting to gain a better understanding of the themes the Board believes are important to include in the next strategic plan.

The Committee will hold an in-person meeting in October to discuss the strategic plan and to discuss the feedback received during regional meetings.

Upcoming Meetings

- August 14, 2023
- August 18, 2023
- September 8, 2023
- September 22, 2023
- October 10, 2023
- November 6, 2023

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jim Sharrock
 - Jerry McCauley
 - Linda Cendales
 - Manish Gandhi
 - Melissa McQueen
 - Richard Formica
 - Silas Norman
 - Valinda Jones
 - Wendy Garrison
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Bonnie Garcia
 - Christopher McLaughlin
 - Daniel Thompson
 - Frank Holloman
 - Shannon Taitt
 - Suma Nair
- **UNOS Staff**
 - Anna Messmer
 - Cole Fox
 - Dale Smith
 - Jacqui O'Keefe
 - Jason Livingston
 - Lauren Mauk
 - Liz Robbins Callahan
 - Maureen McBride
 - Michael Ghaffari
 - Rebecca Brookman
 - Roger Brown
 - Susan Tlusty
 - Susie Sprinson
 - Tiwan Nicholson
 - Tony Ponsiglione
 - Trish Jasion
- **Other Attendees**
 - Andrew Flescher
 - Jennifer Prinz