

OPTN Executive Committee

Meeting Summary

June 16, 2023

Webex

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via Webex teleconference on 06/16/2023 to discuss the following agenda items:

1. Separation of OPTN and OPTN Contractor Boards of Directors
2. Closed Session

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

1. Separation of OPTN and OPTN Contractor Boards of Directors

Jason Livingston, General Counsel, presented on the separation of the OPTN Board of Directors from the OPTN Contractor's Boards of Directors. A new OPTN Contact task requires the contractor to provide an OPTN Board Independence Plan. Mr. Livingston explained that the goals of the project include allowing the two Boards' to be independent from one another, ensuring that the plan complies with the law, and ensuring that the plan will aid the governance structure that serves the transplant community. Additionally, the plan should serve the transplant community, limit the liability for OPTN Board members and volunteers, allow for business continuity that does not depend on the OPTN Contractor to provide structure of continuity, preserve and protect the OPTN's assets, and ensure the government has appropriate oversight over the OPTN.

Mr. Livingston presented the requirements of the board independence plan stated in the contract modification. Incorporating the OPTN as an independent legal entity has been discussed in depth and has now become a requirement of the independence plan. The task asks what activities are required to incorporate the OPTN. Mr. Livingston noted that regular engagement with HRSA during the incorporation process will be an essential part of the independence plan, as HRSA's approval and feedback is key. HRSA has asked the Contractor to produce a risk register to ensure legal protections are adhered to for Board members. These protections are intrinsic for a corporation, as a corporate entity provides individuals protection from liability.

HRSA has also asked the contractor to consider procedures for the OPTN Board to appoint and evaluate the OPTN Executive Director, including whether this person will be employed by the contractor(s) and how this individual would interact with the contractor(s). Mr. Livingston explained that the Executive Committee will be able to discuss and propose potential solutions to these questions. Another requirement of the independence plan asks the contractor to consider how the Board's resource needs will be met to oversee the OPTN. The Executive Committee was also asked to consider how they plan to ensure all OPTN Board members understand their fiduciary responsibility to the OPTN, how they evaluate the impact of the change to the Board on all OPTN functions, and how the committee plans to propose potential changes to the OPTN Contract. Mr. Livingston explained that OPTN Bylaws will need to be modified. The plan should also address how to indemnify officers and directors for any claims that arise from their volunteer service. Currently, the OPTN Contractor provides protection for any

volunteers, and this is something not currently included in the OPTN Bylaws or Charter. The independence plan should also include a proposal on how to educate stakeholders and members of the OPTN. These members would be part of a new corporation, so the Executive Committee must consider how members are educated on the new structure and governance of the OPTN.

Mr. Livingston noted that the current state of the OPTN Contract specifies that the contracting organization serves as the OPTN Board only for the duration and purposes of the current OPTN Contract; this contract requirement is why the OPTN Contractor's Board also serves as the OPTN Board and how the OPTN Board is covered by the shield of liability. Because the contractor provides protection to Board members, the contractor has the derivative right to collect the OPTN Registration Fee, as set forth in the Final Rule. Other tasks delegated to the contractor in the Final Rule include maintaining the OPTN Reserve Fund, however there are limitations on how these funds may be used embedded in the contract. Mr. Livingston noted that OPTN activities are constrained by the OPTN contract. Mr. Livingston laid out the current state of the contract to show how contract terms can potentially constrain OPTN authority and abilities.

Mr. Livingston presented the contractor's proposed plan to separate the Boards. The contractor has identified that the most effective path is to incorporate the OPTN as a private nonprofit entity. This plan would be compliant with NOTA and the OPTN Final Rule. The plan would provide perpetual duration, the OPTN can be permitted to own its' own assets, and the OPTN could be able to provide liability insurance to members and volunteers. This proposed plan provides the independence that was laid out as the strategic anchor, appears to best serve the transplant community, and is compliant with the law.

Mr. Livingston explained that there is currently a two-party relationship that involves the government and a unified OPTN and Contractor. Once there is a third OPTN entity, then this will change the relationship between the two parties. Mr. Livingston explained that this will be a new relationship to navigate and set the authority, responsibility, and accountability between the OPTN and HRSA, and between HRSA and the OPTN Contractor(s).

Key assumptions must be made in order for the OPTN to be incorporated as its own private nonprofit entity. Mr. Livingston explained that these include that the funding of the OPTN contract(s) with the OPTN registration fee will be addressed without a regulatory change, when the OPTN is incorporated then the OPTN will have its own independent counsel, that OPTN policies, bylaws, and charter are all owned by the OPTN and will govern OPTN operations, and that the OPTN Board of Directors will endorse the final independence plan. Mr. Livingston identified the end of the contract period as the date the independence plan would need to be implemented. This implementation date will likely be March 30, 2024.

Summary of discussion:

A representative from HRSA stated that the contractor has been asked to submit a plan as a deliverable, but the implementation of the project is still unclear. HRSA plans to review the contractor's proposed plan and HRSA will then determine the final implementation plan. Another representative from HRSA commented that the Board's endorsement of the plan does not necessarily mean that the plan will be implemented. They stated that the involvement of the Board is important to consider the wishes of the Board, but HRSA will not commit to a transition plan solely because the OPTN Board of Directors endorses it.

A committee member asked if HRSA could collaborate with the contractor from the beginning to develop a plan to separate the Board's instead of going back and forth with feedback. A representative from HRSA responded that HRSA has completed the front-end of laying out the parameters and key

areas that they would like the plan to involve. They stated that one area where more work may need to be done is around state laws of incorporation based on where they choose to incorporate the OPTN.

A committee member asked what this separation meant for the contractor's Board of Directors and asked if this plan is to act as a transition plan. Mr. Livingston responded that this is why the March 30, 2024 date is important because when the next contract period begins, it will be imperative that a plan is in place. Because the contractor's Board currently serves as the OPTN Board, it will be important to separate the two before March 30, 2024.

A member of the committee asked if there was a model the OPTN could potentially mimic. They stated that the contractor has spent time developing a plan as to what they think is best, without hearing input from the government on what is critical from their point of view. They suggested consulting other government agencies that the contractor could sculpt the contract after so that it works best for everyone. A representative from HRSA responded that this is the premise of their request for information so they may learn how to potentially structure the independence plan. The representative also stated that there will be a group conducting stakeholder engagement to collect information and input from Board members. Another committee member commented that HRSA should let the contractor know if there is something critical to include in the plan to ensure the contractor is not working in a vacuum. The representative from HRSA responded that this is why HRSA is coming to the OPTN Board of Directors for their input, because they know that they are the experts in the field. They stated that HRSA thought making the two Boards independent from one another would be a quick task, but they are learning that the process is much more complex than they originally assumed.

Next Steps:

Contractor staff will prepare and submit the contract deliverable to HRSA by July 14; HRSA will then provide feedback on the Board Separation Plan to the contractor. The contractor will address feedback and submit the revised Board Independence Plan within ten days of receiving feedback from HRSA. The Board will be consulted on how to best incorporate feedback from HRSA on the plan.

2. Closed Session

The committee met in a closed session.

Attendance

- **Committee Members**
 - Brad Kornfeld
 - Dianne LaPointe Rudow
 - Gail Stendahl
 - Irene Kim
 - Jeff Orłowski
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Lloyd Ratner
 - Matthew Cooper
 - Valinda Jones
- **HRSA Representatives**
 - Christopher McLaughlin
 - Frank Holloman
 - Julie Ross
 - Manjot Singh
 - Pilar Martinez
- **UNOS Staff**
 - Anna Messmer
 - Dale Smith
 - David Klassen
 - Jason Livingston
 - Julie Nolan
 - Liz Robbins Callahan
 - Maureen McBride
 - Morgan Jupe
 - Tiwan Nicholson
 - Tynisha Smith
- **Other Attendees**
 - Katherine Milka