

## **OPTN Executive Committee**

### **Meeting Summary**

**April 17, 2023**

**Webex**

**Jerry McCauley, MD, MPH, FACP, Chair**

### **Introduction**

The OPTN Executive Committee met via Webex teleconference on 04/17/2023 to discuss the following agenda items:

1. HRSA OPTN Modernization Initiative

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

#### **1. HRSA OPTN Modernization Initiative**

Dr. Jerry McCauley, Chair of the Executive Committee, welcomed the members of the committee to the meeting and explained that purpose of the meeting was to discuss HRSA's OPTN Modernization. Dr. McCauley noted that this meeting was scheduled to discuss how that initiative may impact the OPTN and the Board of Directors.

Representatives from HRSA explained that the purpose of the modernization initiative is to increase high quality organ donation and transplantation. They stated that the initiative is centered on the needs of patients and their families, equitable access to transplantation, and safety and health outcomes. Their announcement highlights five key areas of reform: technology, data transparency and analytics, governance, operations, and quality improvement and innovation.

Ms. Valinda Jones, Vice President of Patient and Donor Affairs, shared a summary of the call that was held with patient volunteers on March 31, led by Ms. Jones and Dr. Dianne LaPointe Rudow, Vice President of the OPTN Board of Directors. The call was held to address questions from patient volunteers about the modernization initiative. Ms. Jones shared key questions and concerns expressed by patients during that call.

Mr. Jason Livingston, Chief Legal Officer and General Counsel, presented on individual liability for the OPTN Board of Directors. Mr. Livingston explained that volunteers of the OPTN have asked what their liability they will be exposed to if the OPTN governance model changes. Mr. Livingston explained that when someone is a director of a corporation, the corporation provides a shield of liability. This means that that officers and directors of the corporation are not personally liable for the actions of the corporation. Currently, the OPTN is not a legal corporation and volunteers are covered by the OPTN contractor. Therefore, if OPTN volunteers are not covered by the OPTN contractor, and if the OPTN is sued, each individual director would be named as a defendant. Mr. Livingston explained that potential solutions include changing the OPTN Final Rule to extend government immunity to the OPTN, incorporating the OPTN as an independent private nonprofit entity, or to deal with individual liability issues by obtaining insurance policies for all 42 individual directors each year. Mr. Livingston explained that the preferred solution would be to incorporate the OPTN as a separate entity to provide a corporate liability shield for all volunteers of the OPTN.

Membership is also important to consider when it comes to incorporating the OPTN. Historically, members have been volunteers of both the OPTN and the contractor. If a new entity is formed, members would have to apply to become members of the new OPTN entity. This would be a fairly simple process, but if the entity continuously changes, then members will have to change their membership to the entity becoming the next OPTN. Having a single OPTN entity where members are members provides continuity in their membership and continuity in the identity of the OPTN. If the OPTN were a separate entity, then this could provide members with a single corporate insurance policy that would provide appropriate coverage for those volunteers.

The challenges that come with incorporating the OPTN as its own entity, is that once the OPTN is a separate entity, they would have to work to rebuild the relationship between the OPTN and the government in terms of delegation of duties and who is the responsible party in particular situations. The second relationship that would need be rebuilt is between the OPTN and one or more OPTN Contractors.

#### Summary of discussion:

A committee member asked if HRSA could elaborate on the five key focus areas they identified. They asked if the key focus areas will each be different contracts or if they were subject matter areas where improvements could be made. Frank Holloman, Director of the Division of Transplantation, explained that HRSA sees this announcement as the beginning of the initiative. He stated that the initiative is an iterative, interactive multi-year process. He compared the process of analysis to the evaluation that was done when reviewing OPTN regions. HRSA does not want any disruptions to the system and they plan to take a systematic approach and that the five pillars of focus serve as an overarching governance.

A committee member asked that since the comparison was drawn between the analysis of regions and the initiative from HRSA, will the OPTN be a part of the process. They specifically noted that when it came to the analysis of mapping the OPTN regions, that the OPTN Board of Directors ultimately were the ones that decided to keep the regions as they were. Mr. Holloman said that the OPTN and OPTN stakeholders will have input in the process. He said that any decisions will ultimately be made by HRSA.

A committee member asked where patients and other stakeholders can submit their feedback to HRSA about the modernization initiative. Mr. Holloman explained that HRSA is working on creating a site for stakeholders to provide feedback on the modernization activities.

A committee member asked about the messaging HRSA plans to present to the public when it comes to the modernization initiative. They emphasized the importance of the public recognizing the partnership between HRSA and the contractor. They asked the representatives from HRSA what their plan is moving forward to ensure that the OPTN Contractor is not independently responsible for defending transplant system without recognition or appreciation. They asked how HRSA plans to prevent this moving forward with the modernization, and how they plan to make the partnership more visible to show that the success of the transplant system is a result of the successes of the partnerships throughout transplantation. Mr. Holloman explained that he was not going to weigh in on anything political, but HRSA has created a diagram to show the relationship between the OPTN, HRSA and the contractor. He continued that HRSA has never shied away from discussing the contractor, and that they understand the valuable role the contractor plays within the OPTN. Mr. Holloman stated that how people perceive the roles between the three entities is out of their control. Another committee member commented that although they may not be able control the media, the community can do a better job of controlling the narrative and clarifying misconceptions. It is important to try and correct misinformation, particularly for patients. Mr. Holloman said that because HRSA is part of the government, they do not usually shy away from refuting inaccurate reports and they use a positive approach in doing so.

A committee member asked how HRSA plans to coordinate all these efforts, especially if there are multiple contractors interacting with each other. Mr. Holloman said that HRSA recognizes the importance in coordinating efforts, as they currently coordinate the work of the OPTN and the SRTR. The committee member commented that bringing all the contractors together periodically, so everyone is on the same page, is important.

When discussing the OPTN Board of Directors individual liability, a committee member asked how coverage is applied to OPTN committee members. Mr. Livingston explained that the present model provides limited liability to all volunteers for the OPTN. He explained that if the OPTN contractor serves as the OPTN, all volunteers are shielded. Currently, all volunteers are also covered under the contractor's insurance policy. Another committee member commented that it is important the OPTN make these arrangements sooner rather than later to ensure that appropriate coverage is provided to volunteers. Another committee member asked if HRSA and the OPTN could create action steps of what members can expect next when it comes to their individual liability.

A committee member asked for some historical examples or context when it comes to the current litigation that the organization is facing. They asked how Board or Committee members who author these policies may be named personally in a lawsuit and how this would affect those volunteers. Mr. Livingston explained that currently, everyone is covered under the current model. The committee member then asked what happens to a Board member's liability coverage once their term is over. Mr. Livingston explained that as long as there is an entity, only the entity will be sued and the individual does not need to worry about their coverage once their term is over. A representative from HRSA explained that originally, the modernization initiative grew out of the idea to split the OPTN and OPTN contractor Board of Directors as a way to eliminate any potential conflicts of interest.

A committee member commented that it is important to address the role of volunteers in the modernization initiative. It is important to ensure they are being protected and looked after so the integrity of the OPTN is upheld. A committee member asked how HRSA envisions managing multiple contracts with the new initiative and how they plan to prevent silos in process and delays to ensure an efficient system without any disruptions. A representative from HRSA commented that they are mindful about using multiple contractors. They noted that the OPTN is still a single system and they plan for the OPTN to speak in one voice.

A committee member asked what will happen to the Board and Committees under the new structure. They asked if the structure will stay the same and the new contractor will oversee them, or whether there will be new volunteers if there is a change in contractor. The committee member also asked if the same rules will apply for structure and process, and whether the same policies and bylaws will be in place. A representative from HRSA responded that the Board and Committees will continue to operate normally, other than HRSA determining a clear legal liability for volunteers. If there is a change in contractor, this will not stop the Board's current or planned work. They also stated that the same policies and bylaws will be in place. The relationship will be a triangle between HRSA, the OPTN, and the OPTN contractor(s); HRSA will work directly with the OPTN contractors and with the OPTN. HRSA also plans to add more detail to the OPTN Executive Director's role and emphasized how important this role is in the new plan.

A committee member asked whether the site surveys for transplant centers and OPOs will remain under the OPTN. A representative from HRSA responded that yes, this will still be OPTN data and that the policies in place to dictate post implementation monitoring requirements will stay the same.

The meeting was adjourned.

## Attendance

- **Committee Members**
  - Dianne LaPointe Rudow
  - Irene Kim
  - Jeffrey Orłowski
  - Jerry McCauley
  - Jim Sharrock
  - Linda Cendales
  - Lloyd Ratner
  - Matthew Cooper
  - Valinda Jones
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Frank Holloman
  - Shannon Taitt
- **UNOS Staff**
  - Alex Tulchinsky
  - Anna Messmer
  - Dale Smith
  - David Klassen
  - Jacqui O'Keefe
  - Jason Livingston
  - Liz Robbins Callahan
  - Maureen McBride
  - Morgan Jupe
  - Roger Brown
  - Ryan Ehrensberger
  - Susie Sprinson
  - Tony Ponsiglione