OPTN Board of Directors Meeting Summary February 27, 2024 Webex

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, President Richard Formica, MD, Vice President

Introduction

The Board of Directors met via Webex on 02/27/2024 to discuss the following agenda items and public comment items:

- 1. Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards*
- 2. Updates from the President
 - a. Expedited Placement Variance Proposal
 - b. Expeditious Task Force
 - c. HRSA Data Directive
 - d. Executive Committee Work Groups

The following is a summary of the Board of Directors discussion.

1. Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards*

Dianne LaPointe Rudow, OPTN President, presented the proposal to address the relationship of the OPTN and the OPTN Contractor Boards. Dr. LaPointe Rudow highlighted that current language in OPTN Bylaws, Article III 2.8, requires that the OPTN Board of Directors is elected in parallel with and using the same procedures as the contractor's Board of Directors. She explained that removing this language aligns with HRSA's goals of the OPTN modernization initiative and recently released draft request for proposals (RFPs) and helps to eliminate real or perceived conflicts or potential conflicts of interest. Dr. LaPointe Rudow shared the current language in OPTN Bylaw 2.8 and the proposed modifications.

Dr. LaPointe Rudow shared the timeline of the proposal and noted that the Board would be asked to take action to release the proposal for special public comment. Dr. LaPointe Rudow highlighted potential next steps if the Board decided to approve the proposal for special public comment. She noted that if the Board approved the proposal for special public comment, there would be a 2-week special public comment period from February 28 to March 13, 2024.

Summary of Discussion:

The Board discussed the language in the draft bylaw changes and suggested minor changes to the language. A representative from HRSA suggested modifications to the language to align with the Securing the OPTN Act that was recently signed into law. The Board discussed different ways to revise the language, and the Board decided to include language that was directly from NOTA. Changing the language to match what is written in NOTA, the proposed bylaw was changed to replace "contracted" with "awarded grants, contracts, or cooperative agreements to support the OPTN". Staff noted that this language was sufficient from a legal perspective.

Vote:

The Board approved the following:

RESOLVED, the OPTN Board of Directors approves distributing the Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards for a special public comment period starting on February 28, 2024 and ending on March 13, 2024.

2. Updates from the President

Dr. LaPointe Rudow shared multiple updates with the Board of Directors.

Expedited Placement Variance Proposal:

Dr. LaPointe Rudow presented an update on the Expedited Placement Variance Proposal. She explained the next steps include the Executive Committee clarifying the proposal and discussing potential policy changes. She noted that in order to clarify the proposal, the Expeditious Task Force will identify potential protocols. Dr. LaPointe Rudow highlighted that the Executive Committee will discuss public comment feedback during their next meeting, and that there will be a public town hall to discuss the proposal in depth with the community. Dr. LaPointe Rudow explained that after the town hall, the Executive Committee will discuss potential changes to the proposal.

Summary of Discussion:

There were no questions or comments from the Board.

Expeditious Task Force:

Dr. LaPointe Rudow shared an update on the work of the Expeditious Task Force. She shared that the Task Force currently has a work group exploring bold aims to help increase transplant growth, a work group analyzing organ non-utilization, and a work group analyzing efficiency. Dr. LaPointe Rudow noted that all these work groups are creating dashboards to measure progress, performing research on non-utilization, and that the Task Force has plans to perform prospective qualitative research to look at organs with a high-risk of non-use. Dr. LaPointe Rudow highlighted the collaboration among the Task Force and other stakeholders in the community, including different government groups, medical and scientific societies, and other community members, to ensure there are diverse perspectives throughout the process.

She explained that the Task Force is currently creating a work group to help secure commitments throughout the community. She explained that the Task Force and the OPTN can try and create changes throughout the system, but unless there are commitments from the community, then the goals and bold aims of the task force are not going to be met. Dr. LaPointe Rudow shared that the task force is hosting a "Transplant Growth Collaborative" where senior leaders from hospitals will be invited to hear from speakers on behalf of the task force. She noted that during these events they will discuss opportunities and barriers to growth, effective practices, and seek specific commitments from attendees. She shared that the work group is seeking OPTN support for these member-hosted events, celebration of and recognition for the participants, and consideration for further collaboration and resources.

Summary of Discussion:

There were no questions or comments from the Board.

HRSA Data Directive:

Dr. LaPointe Rudow provided an update on the Data Directive from HHS that the OPTN received on February 5, 2024. Dr. LaPointe Rudow shared that an initial OPTN communication was sent to the OPTN community about the data directive. The OPTN also met with HRSA on February 14 about the directive. She shared that HRSA requested that staff provide input on two pre-waitlist forms, aligned with the Data Advisory Committee's (DAC) feedback and form instructions. HHS also requested that OPTN staff provide a ventilated patient form that would combine the two drafted forms HRSA provided. The OPTN is requested to provide information on the forms by February 21.

Dr. LaPointe Rudow shared that the OPTN expects the 60-day federal notice to be posted in spring 2024. She explained that a collective OPTN response will be drafted and finalized by the Executive Committee.

Dr. LaPointe Rudow explained that based on community feedback, HRSA is encouraged to provide timely information on next steps and opportunities for engagement. She noted that the DAC chairs received feedback from the community that some of the messaging surrounding the directive may be confusing, and although HRSA has been presenting information during regional meetings, the community is still unfamiliar with the HHS data directive approach. Dr. LaPointe Rudow shared that it is important for the OPTN to provide information to the community on how the public can comment on the proposed changes, and that the OPTN should provide an assessment of the directive. Dr. LaPointe Rudow shared that after the 60-day comment period on the federal register, the Executive Committee will discuss next steps on revisiting the MPSC's concept paper on "Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection."

Summary of Discussion:

A Board member asked for clarification on the timeline noted for spring 2024. A representative from HRSA responded that they hoped to have a public comment period in June and July 2024.

A Board member asked if the OPTN would consider holding a parallel special public comment period to increase awareness to OPTN members on the need to submit comments on the data directive through the Federal Register. The Board member suggested that if the data directive is out for public comment during an OPTN Regional Meeting cycle, then HRSA should speak to the directive during these meetings. A representative from HRSA commented that there will be two public comment periods within the OMB process. They explained that the 60-day notice will likely be released sometime in March 2024, and then the 30-day notice should be in later spring 2024. They commented that the expectation for the 60-day notice will be to provide the community with more information, including more information on the data collection forms requested.

A Board member asked if the OPTN Network Operations Oversight Committee (NOOC) will analyze the notice. They commented that the initiative to collect more data did not mention these data being gathered electronically and focused more on developing the two new forms. Dr. LaPointe Rudow commented that it could be beneficial to consult with the NOOC.

Executive Committee Work Groups:

Dr. LaPointe Rudow presented an update on two Executive Committee Work Groups: the Code of Conduct Work Group and the Prioritization Work Group. Dr. LaPointe Rudow shared the project plan for the Code of Conduct Work Group and the progress the group has made since beginning to meet. She shared that the work group has discussed volunteer responsibilities and requirements for public statements to include in the code of conduct. She shared that during their next meeting, the work group will finalize provisions and discuss enforcement options and processes.

Dr. LaPointe Rudow provided an update on the Prioritization Work Group. She shared the problem statement the work group is considering, the goal of the work group, and the timeline of the work group's plan. Andrea Tietjen, Chair of the Prioritization Work Group, commented on the work that the group has been focusing on, including analyzing the current process and ensuring that the prioritization process is sound and transparent. Ms. Tietjen stated that much of the work group's focus will be around

refining the process, communicating what the process is, and having objective tools to demonstrate a thoughtful review. Ms. Tietjen shared that the work group hopes to strengthen oversight throughout the prioritization process to ensure that the OPTN is utilizing its resources in the most efficient way possible.

Summary of Discussion:

There were no questions or comments from the Board.

Upcoming Meetings

• March 26, 2024

Attendance

- Board Members
 - o Alan Langnas
 - o Andrea Tietjen
 - o Andrew Kao
 - o Bryan Whitson
 - Christopher Jones
 - Colleen McCarthy
 - o Daniel Yip
 - o Dianne LaPointe Rudow
 - o Emily Blumberg
 - o Erika Demars
 - o Evelyn Hsu
 - o George Surratt
 - o Ginny McBride
 - o Jen Lau
 - o Jerry McCauley
 - o Jim Sharrock
 - o Julie Spear
 - o Kelley Hitchman
 - o Ken McCurry
 - o Laura Butler
 - o Laurel Avery
 - o Linda Cendales
 - o Luis Hidalgo
 - o Mark Barr
 - o Maryjane Farr
 - o Meg Rogers
 - o Melissa McQueen
 - o Michael Kwan
 - o Reginald Gohh
 - o Richard Formica
 - o Silas Norman
 - o Stuart Sweet
 - Wendy Garrison

HRSA Representatives

- Adrienne Goodrich Doctor
- o Frank Holloman

• UNOS Staff

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- o Anna Messmer
- o Jacqui O'Keefe
- o James Alcorn
- o Morgan Jupe
- Nadine Hoffman
- o Rebecca Murdock
- o Roger Brown
- o Susie Sprinson

- o Tiwan Nicholson
- o Trish Jasion