



March 13, 2024

Dianne LaPointe Rudow, DNP
Chair
Executive Committee
Organ Procurement and Transplantation Network
Mount Sinai Medical Center
1425 Madison Avenue
New York, NY 10029

RE: Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards

Dear Dr. Rudow:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) Executive Committee's request for feedback on the "Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards."

ASN strongly supports the change to have an OPTN Board of Directors that is separate from the boards of directors of any OPTN contractors. Maintaining an independent board will align with widely recognized best practice for good governance, help create greater accountability for the various important functions of OPTN, and ensure appropriate conflict of interest management in the leadership of our nation's organ and transplantation network under the U.S. Department of Health and Human Services.

However, despite supporting this approach, ASN has questions about the timing of the proposed change. The shift to an independent board is a major change to the OPTN—and an important one—but a change that must be planned and managed with care to ensure an optimal design and function of the new structure, as well as to ensure the continuity of all OPTN functions throughout the transitional process. It is not clear that the proposed timeline of Saturday, March 30, 2024, would allow for this kind of an approach. It is also not clear why the timeline for public comment was limited to just Wednesday, February 28, through Wednesday, March 13, a notable six days prior to the end of the OPTN winter comment period. It is ASN's understanding that neither the Health Resources and Services Administration (HRSA) nor Congress have called for this shift to take place on this timeline.

The shift to an independent board necessitates the formation of a new legal entity for OPTN, including ensuring procuring indemnification insurance and other legal protections for OPTN board members. It is not evident to ASN that this important process has been completed. It seems it would provide more stability for OPTN and for the Board and HRSA to plan to make the shift proposed for Saturday, March 30, 2024, at a future date when a new legal entity is ready, protecting the board members.

While the proposal notes that this shift is being made proactively in anticipation of new OPTN contracts, the final contracts have not yet been released and the deadline to apply shared in the draft form of the contracts was Tuesday, June 18, 2024. This date is six weeks after the proposed board separation, leaving ample time for this change to occur and set this precedent, as the Board desires, before new contracts are awarded.

ASN appreciates that OPTN has created an opportunity for public comment on this important change, but the society is concerned it does not have a full understanding about the context of the request. ASN is aware that UNOS has been in negotiations with HRSA regarding extending the current contract (which ends on Friday, March 29, 2024). While the status of those negotiations is not publicly known, it is also not clear in the proposal what if any connection between the slated end of that contract and the proposed date for board separation exists in the Board's mind. If the current contract is extended, presumably that would allow UNOS to continue providing the important legal protections for Board members, which would appear to be a potential reason not to make the board separation change on March 29. ASN recognizes it is possible that HSRA has other plans for the future of the OPTN board that the society is not privy to at this moment and looks forward to more information being shared.

Again, ASN strongly supports a fully independent OPTN board but questions why this change is being made at this time with such an expedited timeframe.

Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,

A handwritten signature in dark ink, reading "Deidra C. Crews". The signature is fluid and cursive, with the first name being the most prominent.

Deidra C. Crews, MD, ScM, FASN
President