

May 22, 2024

BY ELECTRONIC MAIL

Suma Nair
Division of Transplantation
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Nair,

On behalf of the OPTN Leadership, we would like to thank you for taking the time to meet with us in person this week. We found the morning session, devoted to reviewing the Performance Work Statement for the extension contract with UNOS and HRSA, very informative. We look forward to participating in similar meetings in the future. The morning meeting is a tangible example of the value of a true collaborative partnership between HRSA and the OPTN.

As such, we left the morning session believing that the OPTN Leadership and HRSA share a common goal for the future state of the United States transplant system in which the OPTN Board of Directors plays a critical role in modernization and the oversight of the future multivendor contract environment. The morning session left us with confidence that HRSA values the knowledge and experience of the OPTN Board of Directors, and the role we can play, in partnership with HRSA, to create an innovative and transparent system that improves access to transplantation and improved outcomes for patients suffering from end stage organ failure.

In contrast to the morning session, we were quite disheartened by the outcome of our afternoon transition meeting, and we fear that HRSA and the OPTN Leadership are not aligned on how to reach what we believe to be our shared goals. As we stated, we take exception with HRSA backtracking from the statement in your March 27, 2024, letter that HRSA supports “the creation of a separate legal entity to serve as the OPTN, with its own independent Board of Directors, to facilitate independent, transparent, and accountable OPTN governance.” (Emphasis added.) Instead, we believe that the structure proposed by HRSA, i.e., an OPTN that is an amorphous concept, will result in a system that continues to over rely on governmental contractors to be fiduciaries for the transplant community and the patients it serves.

As you know, the OPTN Board of Directors are elected by OPTN members including transplant hospitals, organ procurement organizations, histocompatibility laboratories, and the patient community. As such and as representatives of this community, we are informing you that the structure that you have proposed will undermine the ability of the Board to fulfil its fiduciary duties, which will further destabilize the community trust and will throw into question the ability of HRSA to oversee the operation of the OPTN public private partnership in a manner that promotes the best

interests of the patients we serve. As we stated, we take the position that the Board of Directors for the OPTN needs to be the Board of Directors of the legal entity that is the OPTN in order to hold OPTN contractors accountable for optimal system performance, support ongoing member quality improvement and drive the innovation needed to make the transplant ecosystem better.

As such, we have summarized the issues that we believe must be resolved in short order to move forward with a strategy of communicating to the transplant community that the OPTN Leadership is in agreement and aligned with HRSA:

- The independent entity must be the OPTN and not the OPTN Board of Directors.
- The independent OPTN must include the committees that work with the BOD to develop policy, perform the work of the OPTN and provide quality oversight to ensure the safety and care of transplant candidates, recipients and living organ donors and honor the gift of deceased organ donors.
- The OPTN must be a membership organization as implied in the Final Rule 121.3 paragraph B Line 1: The OPTN shall admit and retain as members the following; all Organ Procurement Organizations, Transplant Hospitals participating in Medicare or Medicaid, and other organizations, institutions, and individuals who have an interest in organ donation or transplantation.
- While the salary of the future OPTN Executive Director may be paid by and through one of the contractors, we believe that a mechanism must be in place to ensure that the executive director (and certain staff) are considered and treated as independent employees of the OPTN entity and that their allegiance and alliance is to the OPTN and not the contractor who is responsible for paying their salary.
- The OPTN registration fees must be paid to the OPTN, as required by the final rule, and distributed to OPTN contractors with HRSA's oversight and approval of submitted invoices.
- The OPTN and HRSA must agree upon memorandums of understanding to guide our current and future partnership, demonstrating that there is substantive public private partnership that will direct current and future contractors in the execution of tasks in service of the OPTN and the transplant community.
- The OPTN Board of Directors, Committee volunteers and participating community members require the legal and liability protections provided by a legal corporation.

We eagerly anticipate, in the spirit of collaboration, our future meetings to achieve a satisfactory agreement on the stated issues that serves our patients in the manner they deserve.

Sincerely,

The OPTN Transition Work Group

Dianne LaPointe Rudow, Richard Formica, Andrea Tietjen, Lloyd Ratner, Stuart Sweet, Ginny McBride, Jim Sharrock

Exhibit 2



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May 28, 2024

Dear Colleagues:

For the past year, the OPTN Board of Directors has embraced the blueprint for OPTN Modernization initially announced by HRSA on March, 22, 2023 and as mandated by modifications under the Securing the US Organ Procurement and Transplantation Act. Energized by the possibility of increasing access to transplantation and improving outcomes for patients suffering from end-stage organ failure, the OPTN Board members have attended and participated in industry days, provided oral and written feedback on the RFAs released earlier this year, and until recently been working collaboratively with HRSA to establish an independent OPTN Board and OPTN that is fully separated from the current and future contractors. In fact, we have and continue to support the concept set forth in the March 27, 2024 letter from HRSA Associate Administrator Suma Nair in which she states that HRSA is supporting “the creation of a separate legal entity to serve as the OPTN, with its own independent Board of Directors, to facilitate independent, transparent, and accountable OPTN governance.”¹

With this proposed structure in mind, the OPTN Board of Directors established the OPTN Transition Task Force (comprised of those Board Members who are signatories to this letter and who represent various perspectives of the organ transplant community) to work with HRSA and its various contractors with the goal of establishing a fully independent OPTN and OPTN Board of Directors by June 28, 2024.

Until recently, we were optimistic that we would be able to achieve this goal but in light of recent interactions and meetings with HRSA, we fear that we will be unable to reach this goal within the proposed time frame (i.e., June 28, 2024) and we are concerned that if HRSA continues to not engage with us in meaningful dialogue on the fundamental issue of what constitutes the OPTN, then we may never reach this goal.

Specifically, over the last three weeks, HRSA has backpedaled and stated that it no longer supports the idea that the new legal entity will serve as the OPTN. Without input, consultation or agreement of the OPTN Board of Directors or the OPTN Transition Task Force, HRSA has been working independently to create a structure in which the OPTN is a loose and undefined association of government and non-government organizations. They plan to form the new legal entity as a formality solely to consist of the Board of Directors. The role of the Board would be extremely restricted, with only limited authority on a narrow set of issues (e.g., limited to only organ allocation policy development and member oversight).

¹ Letter from Suma Nair PhD, MS, RD, Associate Administrator, Health Systems Bureau, to Dianne LaPointe-Rudow ANP-BC, DNP, FAA, OPTN President, United Network for Organ Sharing (Mar. 27, 2024), at <https://www.hrsa.gov/sites/default/files/hrsa/about/optn-board-separation-plan-letter.pdf>. (Emphasis added.)

The OPTN Transition Task Force believes that HRSA's proposed plan: (1) marginalizes the future OPTN Board of Directors and the OPTN Committees; (2) minimizes the role of the patients, transplant physicians, surgeons, other medical professionals, OPO representatives, and other key stakeholders who volunteer their time and expertise in support of the OPTN mission; (3) raises questions about the role of OPTN members, and (4) jeopardizes the Governmental/OPTN public-private partnership that is necessary for the success of the OPTN modernization initiative.

Despite our repeated requests, HRSA has not provided the OPTN Transition Task Force with a rationale, or legal basis, for this new structure nor have we been provided with any documents that would set forth a meaningful definition or explanation of this proposed concept/structure. As of the date of this letter (i.e., less than a month from the June 28, 2024 goal), we have not been provided with drafts of any documents necessary for the operation of this new entity such as: Articles of Incorporation; updated and revised By-Laws; Charters for the various Board of Director Committees; and a new (and what we believe to be fundamental) document that will serve as a Memorandum of Understanding setting forth the roles, responsibilities and relationships by and among HRSA, the various contractors and the OPTN Board of Directors.

Based upon the activities of the last few weeks, the OPTN Transition Workgroup urgently requests your help. We need members of the transplant community to make their opinions known and to impress upon HRSA to:

- (1) honor its commitment to establish a legal entity that will serve as the OPTN with a Board of Directors, Executive Director, and small support staff, that is fully independent of the contractors and the government, but which will work alongside HRSA to ensure appropriate oversight, and
- (2) actively engage in meaningful dialogue, collaborate with and listen to those volunteers who represent patients, transplant centers, OPOs, and professional societies who will be instrumental in modernizing our system to better service patients suffering from end-stage organ failure.

As the members of the OPTN Transition Work Force, we believe that the model originally proposed by HRSA in its March 27, 2024 letter provides the most effective way for the OPTN and its Board of Directors to bring its vast knowledge and experience, and to partner with HRSA, in achieving a shared vision of a modernized transplant system that provides safe and effective care for the patients and donor families it serves across the United States. To that end we are hoping to have a positive working relationship with HRSA moving forward.

Sincerely

OPTN Board of Directors Transition Work group

Dianne LaPointe Rudow
Richard Formica
Virginia McBride
Lloyd Ratner
Jim Sharrock
Stuart Sweet
Andrea Tietjen

Exhibit 3

RON WYDEN, OREGON, CHAIRMAN

DEBBIE STABENOW, MICHIGAN	MIKE CRAPO, IDAHO
MARIA CANTWELL, WASHINGTON	CHUCK GRASSLEY, IOWA
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CATHERINE CORTEZ MASTO, NEVADA	TODD YOUNG, INDIANA
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	JOHN BARRASSO, WYOMING

JOSHUA SHEINKMAN, STAFF DIRECTOR
GREGG RICHARD, REPUBLICAN STAFF DIRECTOR

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

May 2, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health & Human Services
Washington, D.C. 20201

Dear Administrator Johnson:

Since passing the Securing the U.S. Organ Procurement and Transplantation Network (OPTN) Act, we have been closely monitoring the Health Resources and Services Administration's (HRSA) implementation efforts, including its OPTN Modernization Initiative. Accordingly, we write today concerning recent developments and their impact on the modernization initiative, specifically the upcoming final Request for Proposals (RFP), Next Generation contracts, and Board Independence Plan. In light of the upcoming final RFPs, and the forthcoming Next Generation and OPTN Board Support contracts, we write to you to share our recommendations for the implementation of the Securing the U.S. OPTN Act and modernization initiative.

First, we note HRSA's recent announcement regarding the OPTN Board of Directors 90-day plan to create an independent OPTN Board. As discussed in the announcement, HRSA is supporting the creation of a separate legal entity, "with its own independent Board of Directors, to facilitate independent, transparent, and accountable OPTN governance. This entity will be independent of the current OPTN contractor and future OPTN contractors."¹

Additionally, in a recent briefing with our staff, HRSA expressed its plans to clarify the OPTN Board's roles and responsibilities through the new legal entity's designation documents. Specifically, HRSA indicated it plans to define the scope of the OPTN Board's responsibility in relation to policy development and membership criteria development in both the articles of incorporation for the new legal entity and in a Memorandum of Understanding (MOU) between HHS and this new legal entity to designate the entity to serve as the OPTN Board of Directors. HRSA also indicated that this new legal entity will not be independent from regulatory oversight, and that this regulatory oversight, along with HRSA's oversight of the contractors

¹ Letter from Suma Nair PhD, MS, RD, Associated Administrator, Health Systems Bureau, to Dianne LaPointe-Rudow ANP-BC, DNP, FAA, OPTN President, United Network for Organ Sharing (Mar. 27, 2024), at 1-2, <https://www.hrsa.gov/sites/default/files/hrsa/about/optn-board-separation-plan-letter.pdf>.

supporting the OPTN Board and carrying out other OPTN functions, is intended to ensure all OPTN activity is consistent with legal and regulatory requirements.

Based on this information, we believe it is imperative that HRSA do the following as they move forward with this plan:

- Clearly, and publicly, define the relationship between HRSA, the OPTN Board of Directors, and the contractors carrying out the remaining OPTN functions, and HRSA’s oversight of each;
- Clearly define the OPTN Board’s responsibilities in a MOU or other agreement as described at the April 24 briefing with congressional staff. These responsibilities should be in accordance with regulation and include:
 - Developing membership criteria² and
 - Developing medical criteria for allocating organs;³
- Make public the full and complete costs of each contract, and available to Congress upon request;
- Clarify that the new legal entity serving as the OPTN Board is to act only within the terms of the MOU or other agreement, as their authority to establish membership criteria and medical criteria stems solely from the designation provided by HHS, and the new entity must be subject to regulatory oversight; and
- Given the complexity and novelty of this new board structure and the need to disentangle the legal relationship between HHS, the new legal entity, and contractors engaged to support OPTN functions, we strongly encourage HRSA to utilize all available government and non-government expertise in developing these foundational legal agreements.

Secondly, the recent fiscal year 2024 appropriation funding package provided HRSA with an additional \$23 million for the OPTN Modernization Initiative.⁴ You have an obligation to prevent and eliminate fraud, waste, and abuse. Moreover, given the final RFP’s “number and scope of task orders issued is contingent on final Fiscal Year 2024 appropriations,” of which the agency received additional funding, we urge HRSA to consider the following recommendations as it finalizes the RFP and looks to the Next Generation contracts:⁵

² 42 USC 274(b)(2)(B)

³ 42 USC 274(b)(2)(B)

⁴ United States Senate Committee on Appropriation, *Senate Approves Final FY24 Funding package in Overwhelming 72-24 Vote* (Mar. 23, 2024), <https://www.appropriations.senate.gov/news/majority/senate-approves-final-fy24-funding-package-in-overwhelming-74-24-vote>; see also Congressional Record, United States House of Representatives, Title II – Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), *Organ Transplantation Modernization Initiative* (March 22, 2024), at H1888, <https://www.congress.gov/118/crec/2024/03/22/170/51/CREC-2024-03-22-bk2.pdf> (*Organ Transplantation Modernization Initiative*—The agreement includes an increase of \$23,000,000 to support this initiative as described in the fiscal year 2024 budget request and in accordance with P.L. 118-14).

⁵ General Services Administration, System for Award Management (SAM), *HRSA OPTN Board of Directors Support*, RFP No. 75R60224R00009 (Feb. 5, 2024), <https://sam.gov/opp/e4fb45f6e5d54a84adbce1602767c52/view#history>; see also General Services Administration, System for Award Management (SAM), *HRSA OPTN Board of Directors Support*, RFP No. 75R60224R00009, *HRSA Organ Procurement and Transplantation Network Modernization Initiative*,

- HRSA should amend both the Board Support and Operations RFPs to create a single Board and Committee Support contract. This change would ensure that the OPTN policy committees are within the purview of the Board, as defined in the MOU. As you are aware, the role of the committees is to develop policies and make policy recommendations to the Board. We strongly encourage HRSA to consider which committees serve functions within the purview of the OPTN Board, as defined in the MOU, or other legal agreements, and include those committees in a unified board and committee support contract.
- We also encourage HRSA to consider which functions fall outside of the purview of the OPTN Board of Directors and would be better structured in relation to other contracts facilitating other OPTN functions, such as compliance and IT functions.
- HRSA should amend the operations RFP to add a logistics contract or separate task order to ensure competition. Logistics is an entirely separable function from other areas of operations and should be independently bid. Additionally, logistics has been a clear area of failure highlighted by the Senate Committee on Finance’s investigations. Addressing this through the transition contracts will help strengthen the system, and save more lives.
- HRSA should amend the RFP to clarify that task orders will be awarded no more than one year at a time. We are concerned, as are numerous patient groups, that allowing transition contracts to extend up to five years (the length of previous OPTN contracts) increases the risk of delays of modernization contracts and a lack of competition. Although we understand the need for flexibility in the Transition contract period, it is imperative that HRSA look forward to the Next Generation contracts and modernization efforts with competition in mind.
- HRSA should amend the Board Support RFP to define HRSA’s oversight role in the selection of board members, specifically their role in establishing the conflict of interest criteria, as it relates to the contractor’s requirements. The current RFP suggestion of a “special election” could potentially leave power in the hands of industry to choose OPTN board members, therefore making HRSA’s oversight role of this process imperative.

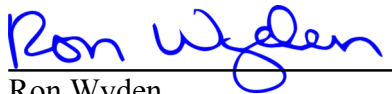
Lastly, we strongly encourage HRSA to seek legal guidance, and provide that guidance to Congress, on how best to utilize OPTN patient registration fees across contracts to support OPTN functions. As you know, the Securing the U.S. OPTN Act directs the Government Accountability Office to analyze the OPTN patient registration fees, but given the time it will take to complete this analysis, utilizing all resources is critical.

Given the scale of these reforms, it is critical that HRSA and the Administration engage in rigorous and transparent oversight of the OPTN Modernization Initiative, specifically holding accountable the entities tasked with oversight of the transplant system. In the entire history of the OPTN, the agency has only ever awarded the OPTN contract to a single entity, the United Network for Organ Sharing. As our bipartisan oversight has shown, UNOS has not performed the job the way they should have and it is time for a change. For the first time in 40 years, the system is able to see real reform and modernization, and HRSA must see it through. We expect these concerns to be addressed in the forthcoming final RFP, as well as the Next Generation

contracts. Therefore, we urge HRSA to address these concerns as they move out of the transition contract phase and into the modernization phase of this process.

Thank you for your attention to this issue. To coordinate HRSA's efforts, please contact Melissa Dickerson of Chairman Wyden's staff at (202) 224-4515 and Tucker Akin of Senator Grassley's staff at (202) 224-0642.

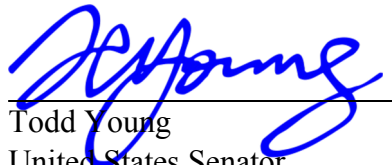
Sincerely,



Ron Wyden
United States Senator
Chairman, Committee on
Finance



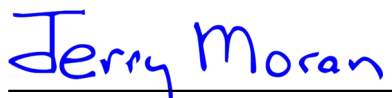
Charles E. Grassley
United States Senator
Member, Committee on
Finance



Todd Young
United States Senator
Member, Committee on
Finance



Elizabeth Warren
United States Senator



Jerry Moran
United States Senator