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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/e4fb45f6e5d54a84adbccce1602767c52/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.

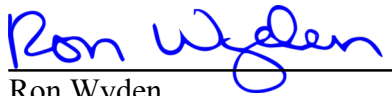
Lastly, we strongly encourage HRSA to seek legal guidance, and provide that guidance to Congress, on how best to utilize OPTN patient registration fees across contracts to support OPTN functions. As you know, the Securing the U.S. OPTN Act directs the Government Accountability Office to analyze the OPTN 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.

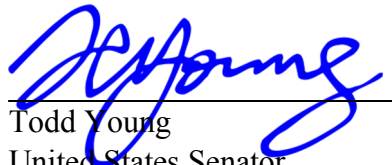
Sincerely,



Ron Wyden
United States Senator
Chairman, Committee on
Finance



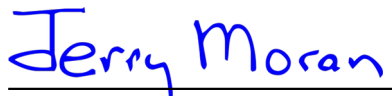
Charles E. Grassley
United States Senator
Member, Committee on
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Todd Young
United States Senator
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Elizabeth Warren
United States Senator



Jerry Moran
United States Senator