

**Subject: Critical Comment Regarding HRSA's Engagement with Patients, Donors, and Donor Families on the OPTN Board of Directors**

Dear Secretary Kennedy:

This letter conveys our serious and ongoing concerns regarding the failure of the Health Resources and Services Administration (HRSA) to implement its OPTN Modernization Initiative in a manner consistent with the needs of transplant patients, donors and families, or in a manner that is respectful of the views of duly elected patient and donor members of the OPTN Board of Directors (Patient and Donor Affairs (PDA) representatives). While we strongly support OPTN modernization, we believe that many of the changes that are being made by HRSA in the name of patients are misguided, ignoring actual patient voices as expressed by elected patient and donor representatives. This conduct is inconsistent with the expressed goal of modernization to make the system more “patient centered.” Our concerns began some time ago and have continued to increase. To emphasize the seriousness of our concerns, we are filing this correspondence as a critical comment under the applicable implementing regulations (the “Final Rule”).

As transplant recipients and family members, some of us have been blessed with the gift of additional time for ourselves or our loved ones as the result of transplantation. Others have lost a loved one who was able to save and improve the lives of others through donation- a beautiful, selfless gift. As OPTN Board members and volunteers, we have dedicated countless hours to improving the journey for our fellow patients and the donor community. Yet, over the past two years, in the name of making the transplant system work better for patients, HRSA has ignored our comments, concerns, and questions, and appears to be intent on implementing a vision for the transplant system that ignores actual patient and donor voices.

HRSA has repeatedly insisted that our service on the OPTN Board is tainted by an unspecified and ill-defined conflict of interest. Continued use of the term “conflicted” to describe transplant patient, deceased donor family, living donor and other representatives on the OPTN Board is unwarranted, undocumented and disrespectful. The Cambridge English Dictionary defines a conflict of interest as “a situation in which a person is in a position to derive personal benefit from actions or decisions made in their official capacity.” As PDA representatives, we are volunteering our time, effort, and lived experience to improve our Nation’s transplant system and to help address the very real concerns of patients. To characterize our involvement as tainted by some unspecified “conflict of interest” is nothing short of defamatory. We categorically reject these false, harmful, and malicious statements--statements that are damaging our reputations, harmful to our families, and misleading to our employers.

In fact, it appears that, for reasons known only to it, HRSA wishes to purge the Board of anyone who was ever on the Board of the United Network for Organ Sharing (UNOS)—or anyone nominated or elected during the past 10 years when the UNOS and OPTN Boards were identical—***even though HRSA’s own rules required that UNOS and OPTN have identical Boards.*** HRSA itself has characterized its decision to make a “clean sweep” of OPTN leadership as one that is required by Congress. While we are extremely troubled by the insertion of political motivation in the selection of Board members who necessarily will be making highly sensitive allocation and other decisions, we must insist that HRSA refrain from characterizing its actions in a manner that imputes a conflict of interest to us and other members of the Board.

The OPTN was established by NOTA as a public-private partnership, and, while the legislation has since been amended to authorize HRSA to engage multiple contractors to support the OPTN, the transplant system can and should continue to operate as a collaborative effort between the OPTN, representing the transplant community, and HRSA, exercising effective public oversight. Transplant patients, their family members, and donor families are—and always have been—fully engaged at many levels in OPTN policymaking, including as Board representatives and Committee members.

Unfortunately, we are concerned that, rather than making the transplant system more “patient centered,” the new “modernized” structure will insulate the transplant system from patient voices. As we understand it, under the new system, the transplant system will be operated by up to fourteen contractors, all of which will be solely responsible to HRSA and none of which have transplant experience or expertise. Policymaking will be made by the OPTN Board, whose new members will be screened and approved by HRSA, and which will operate under the oversight of HRSA. Under this new structure, it is unclear to us how patient, patient family, and donor family voices will be heard, other than through the patient and donor representatives on the OPTN Board.

Our experience over the past several years, as OPTN modernization has unfolded, have left us extremely discouraged regarding whether, and to what extent, patient representatives on the OPTN Board of Directors will be heard:

- Despite urging from the patient and donor community, HRSA failed to include donor family representation or representation from other critical groups (such as thoracic, pediatric transplant families and care-partners) on the Transitional Nominating Committee that will select the slate of new Board members.
- HRSA has misrepresented its communications with the Board regarding the existence of an agreed transition plan to facilitate training of new Board members.
- HRSA has undermined the likelihood of a successful transition by cancelling in-person training of the new Board members, without consultation with the Board.
- HRSA has cut off the OPTN’s ability to communicate its decisions and policies to media and the public, responding to all media inquiries through its own Media Desk, without consultation with or approval of the OPTN Board, Executive Committee, or other OPTN volunteers who might be involved.
- HRSA has required that webinars and meetings be held without allowing the audience to participate live, ask questions in real time, or seek clarifications on statements made.
- HRSA’s interaction with patient and donor representatives has been characterized by open disrespect.<sup>1 2</sup>
- Numerous requests from elected PDA Board members, including concerns and questions, have gone unanswered by HRSA representatives.

We are also concerned about the lack of effective Board support at this critical transitional period. It is our understanding that, while HRSA has engaged a new contractor, American Institutes for Research

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<sup>1</sup> During the December 2024 in-person OPTN Board meeting, PDA Member Dr. Brittany Clayborne, a heart recipient and parent to a pediatric heart recipient, was met with open verbal sarcasm by Dr. Suma Nair.

<sup>2</sup> During the July 2024 American Transplant Congress (ATC), PDA Board Member Julie Spear, a deceased donor mother and non-directed kidney donor, expressed concerns in a Q&A about the lack of transparency on modernization and was outwardly mocked and disrespected by Dr. Suma Nair.

(AIR) to provide Board support, HRSA has not effectively negotiated a transition of data, information, and other systems protocols from UNOS to AIR. Under HRSA's purview AIR has failed to effectively support the Board with respect to relatively straightforward functions, such as scheduling and cancelling meetings, inhibiting effective and coordinated Board decision making. From our vantage point, OPTN Board support has taken a significant step backwards with the retention of AIR as the Board Support Contractor. This lack of satisfactory performance for the simplest of tasks should raise alarm regarding HRSA's contractor selection processes for tasks upon which patient lives depend.

In summary, the persistent issues outlined—including inadequate communication, lack of transparency, disregard for the contributions of PDA representatives, misrepresentations regarding OPTN modernization's focus on patient well-being, and failure to address the genuine needs of transplant donors, patients, and families—are fundamentally unacceptable. Furthermore, government overreach and HRSA's apparent reluctance to acknowledge responsibility for past OPTN deficiencies, coupled with a decade of inadequate oversight, have resulted in the marginalization of true patient voices. It appears that in an attempt to dissociate itself from past OPTN deficiencies and deflect accountability for its lack of oversight, HRSA has concluded that it is necessary to seize complete control over the transplant system. During the process, HRSA has cultivated an adversarial environment that undermines the effectiveness of the OPTN Board, where elected patient and donor representatives are consistently sidelined and ignored, despite their essential role in representing the transplant community.

We believe that HRSA, as the responsible federal agency for OPTN oversight, must take immediate and meaningful action to rectify our concerns and establish a framework of transparency, respect, partnership, and accountability.

Sincerely,

Elected Patient and Donor Affairs Representatives of the OPTN Board of Directors

Jennifer Lau, Parent of pediatric liver transplant patient

Glen Kelley, Heart and kidney transplant recipient/living and deceased donor family member

Kelley Hitchman, Non-directed living kidney donor

George Surratt, Recipient of a liver and kidney transplant

Julie Spear, Deceased donor mother/non-directed living kidney donor

Denise Abbey, Heart transplant recipient

Joseph Brownlee, Parent of two-time pediatric heart transplant recipient

Brittany Clayborne, LVAD & heart transplant recipient/Post transplant lymphoma survivor/Pediatric heart transplant parent/donor family member

Donor Family Member

Macey Levan, Living Kidney Donor

Cc: Thomas Engels, HRSA Administrator  
Dr. Suma Nair, HRSA Associate Administrator  
Dr. Rich Formica, OPTN President  
OPTN Board of Directors