

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

The Honorable Suma Nair
Associate Administrator
Health Systems Bureau
Health Resources and Services Administration/HHS
Rockville, MD

The Honorable Xavier Becerra
Secretary of HHS

CC: Senator Ron Wyden
CC: Senator Charles E. Grassley
CC: Senator Todd Young
CC: Senator Elizabeth Warren
CC: Senator Jerry Moran

Dear Administrator Johnson and Associate Administrator Nair,

We have been monitoring the United States Organ Procurement and Transplantation Network (OPTN) Modernization Initiative as it is being implemented by the Health Resources and Services Administration (HRSA) with intense interest. On behalf of our organizations which represent pediatric transplant recipient patients and families, pediatric transplant candidate patients and families, pediatric transplant professionals, and pediatric hospitals, we are writing to share our concerns and recommendations regarding the implementation of the Securing the U.S. OPTN Act and Modernization Initiative. We have participated in all available opportunities for public comment including the recent Board Separation and Future OPTN Governance Town Hall.

We recommend that HRSA present a clear vision for the future state of the OPTN and transparency at each step of the process of redesign of the OPTN.

Transparency with the organ transplant community, transplant professionals, patients, and families around the plans for the OPTN structure, governance, policy development, and implementation/logistics is key for a successful transition from a one vendor model to a multi vendor model. The OPTN and U.S. transplant system is incredibly complex and without transparency around each step of the process, the organ transplant professionals, who are the subject matter experts and end users, cannot provide constructive commentary around system redesign. HRSA needs to provide a flow chart regarding how policy will be developed, how the OPTN Board of Directors will function, where the OPTN committees will sit, how HRSA will interact with the OPTN Board, and how organ transplant recipients, families, and professionals

will be involved in the future operation of the OPTN. The following practical matters must be addressed:

- Given the June 30th deadline for completing the OPTN Board separation, HRSA needs to provide organizational documents as soon as possible that clarify: 1) the proposed OPTN and OPTN Board structure, including how the OPTN Board will be selected, and 2) details of the relationship between HRSA, CMS, the OPTN Board, the OPTN Committees and the remainder of the OPTN and supporting contractors.
- HRSA needs to provide evidence as soon as possible that they have a commitment from an insurance provider to provide D&O and professional liability coverage for the OPTN Board and Committees for actions taken in policy development, member oversight and other OPTN activities within their purview.
- We are also concerned that HRSA appears to not be fully following the instructions provided by the Senate Finance Committee in their letter from May 2, 2024.¹

The needs of children should be front and center in OPTN modernization. We are concerned that the HRSA contract solicitations do not explicitly request that contractors address this unique population in their applications. References to the National Organ Transplant Act (NOTA), the OPTN Final Rule, the current OPTN bylaws, and the Securing the U.S. OPTN Act within the government contract solicitations are insufficient to highlight this need. NOTA charges the OPTN to "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."² Modernization of the OPTN should explicitly consider how children are structurally protected as part of the system redesign and HRSA must request that future OPTN contracts explicitly address how they will meet the unique organ transplant needs of children in order to fulfill the tasks laid out in the HRSA Contract solicitations.

During this period of disruption and transition, OPTN system stability and patient safety must be the top priority. Ensuring a seamless, well coordinated transition in OPTN contractors is essential to the protection and safety of children who are candidates for organ transplant or recipients of organ transplant. We know that children have the potential to be harmed by even small disruptions to the operation of the organ transplant system. When pediatric donors are scarce, missing even one donor offer can be the difference between life and death. HRSA should acknowledge that this type of structural realignment of contractors and policy has never been done before. There is no template for success nor significant functional knowledge about how to do this outside of current organ transplant professionals and UNOS. This is why transparency about operational plans and opportunities for constant back and forth engagement with transplant professionals is necessary to maintain a high level of system safety and stability during OPTN Modernization.

Pediatric-focused metrics are key to achieving the goals of the OPTN Modernization Initiative. Every key metric which is designed, developed and utilized to monitor OPTN

¹ [Letter](#) from Senate Finance Committee to Administrator Johnson, May 2, 2024.

² National Organ Transplantation Act (NOTA), 42 USC §273 et seq.

performance, safety, and quality must have a pediatric component which explicitly considers childrens' unique healthcare needs. We feel that age adjustments within overall models are often inadequate to consider the unique healthcare needs of children, or other vulnerable populations such as ethnic, racial, or religious minorities. Given that the adult donor and transplant population is so much larger than some of these vulnerable populations, metrics that consider both groups together can create incentives that may improve adult donation and transplantation without any similar improvement to care delivered to pediatric transplant candidates and recipients. System changes must explicitly consider the effects of policy or operational change on the unique healthcare needs of children and other vulnerable populations.

With this letter we offer our time and expertise in implementing the OPTN Modernization Initiative in a way that places children, their families, and all transplant candidates and recipients at the center of decision making.

Sincerely,

[Pediatric Heart Transplant Society](mailto:phtsfexecutivedirector@gmail.com)
phtsfexecutivedirector@gmail.com

[Transplant Families](mailto:hello@transplantfamilies.org)
hello@transplantfamilies.org

[Advanced Cardiac Therapies Improving Outcomes Network](#)

[Alagille Syndrome Alliance](#)

[American Academy of Pediatrics](#)

[Biliary Atresia Research & Education, Inc.](#)

[Children's Cardiomyopathy Foundation](#)

[Children's Hospital Association](#)

[Children's Organ Transplant Association](#)

[Children's Transplant Initiative](#)

[Conquering CHD](#)

[Enduring Hearts](#)

[Hearts for Emma](#)

[IROC Community Engagement Workshop](#)

[Liver Mommas & Families, Inc.](#)

[Mended *Little* Hearts](#)

[North American Society for Pediatric Gastroenterology, Hepatology & Nutrition](#)

[Pediatric Infectious Diseases Society](#)

[Patient, Family and Engaged Partners of SPLIT](#)

[Society for Pediatric Liver Transplantation \(SPLIT\)](#)

[Starzl Network for Excellence in Pediatric Transplantation](#)

[YNOTT Foundation \(Youth Needing Organ & Tissue Transplants\)](#)